SPECTRAL INC
Diagnostics

ANNUAL GENERAL MEETING
MAY 23, 2013

EUPHRATES
A CLINICAL TRIAL IN ADULTS WITH SEPTIC SHOCK AND ENDOTOXEMIA

FORWARD LOOKING STATEMENTS

Certain statements contained in this presentation constitute forward-looking information within the meaning of securities laws. Forward-looking information may relate to our future outlook and anticipated events or results and may include statements regarding our future financial position, business strategy, budgets, litigation, projected costs, capital expenditures, financial results, taxes and plans and objectives. In some cases, forward-looking information can be identified by terms such as "may", "will", "should", "expect", "plan", "anticipate", "believe", "intend", "estimate", "predict", "potential", "continue" or other similar expressions concerning matters that are not historical facts. These statements are based on certain factors and assumptions regarding, among other things, expected growth, results of operations, performance, and business prospects and opportunities. While we consider these assumptions to be reasonable based on information currently available to us, they may prove to be incorrect. Forward looking-information is also subject to certain factors, including risks and uncertainties that could cause actual results to differ materially from what we currently expect. These factors include, among other things, the availability of funds and resources to pursue development projects, the successful and timely completion of clinical studies, and the ability to take advantage of business opportunities, the granting of necessary approvals by regulatory authorities, and general economic, market and business conditions. For more exhaustive information on these risks and uncertainties you should refer to our most recently filed Annual Information Form which is available at www.sedar.com. Forward-looking information contained in this presentation is based on our current estimates, expectations and projections, which we believe are reasonable as of the current date. You should not place undue importance on forward-looking information and should not rely upon this information as of any other date. While we may elect to, we are under no obligation and do not undertake to update this information at any particular time.

Activities since last year's meeting

EUPHRATES Trial:

- Defined the Statistical Analysis Plan and achieved FDA approval for it
- Now managing 36 sites, 40 hospitals
- Enrolment at 116 patients (.22 patients /site/month for entire study (.30 for the first 4 months of 2013)
- Conducted the third Investigators meeting for EUPHRATES
- There were 4 DSMB meetings, including the first interim analysis

Corporate Activities:

- Raised $5.6M CAD above market –Toray now very involved with SDI
- Planned for manufacturing and commercialization scale up
- Hired a VP of Sales and Marketing
- Continued clinical development program for EAA™ and PMX outside of EUPHRATES
- Laid foundation for partnering


THE EUPHRATES TRIAL

EUPHRATES STUDY DASHBOARD
May 22, 2013

Screening/Randomization	Follow-up	28 Day Mortality
Clinically Eligible 272	**Survived to Day 28 167**	**Died before Day 28 69**
EAA™ ≥ 0.6 145	Randomized 71	Randomized 33
EAA™ < 0.6 127	Low EAA™ Screen Failures 82	Low EAA™ Screen Failures 29
	High EAA™ Screen Failures 14	High EAA™ Screen Failures 7
Randomized 120		
Low EAA™ Screen Failures 127	Randomized Ongoing 16	**% Mortality – 28 Days**
High EAA™ Screen Failures 25	Low EAA™ SF Ongoing 16	
	High EAA™ SF Ongoing 4	Randomized 32%
Received IP 117		Low EAA™ SF 26%
Did not receive IP 3	3-Month Follow-up 49 6 Month Follow-up 40 12-Month Follow-up 27	Overall 29%

EUPHRATES TRIAL SITES

Site #	Site Name	Principal Investigator	Lead Coordinator	Nephrologist
1	Cooper Health System	Dr. Phil Dellinger	Christa Schorr	Dr. Larry Weisberg
2	Temple University	Dr. Gerard Criner	Kathleen Mcleer	Dr. Samuels
5	Mayo Clinic	Dr. Kianoush Kashani	Laurie Meade Shonie Buenvenida Lavonne Liedl	Dr. John Dillon
6	UTHSC at Houston	Dr. Kevin Finkel	Beatriz Efron	Dr. Amber Podoll
7	St. John's Mercy Medical Center	Dr. Robert Taylor	Jacklyn O'Brien Catherine Krause	Dr. Mark Ravenscraft
8	U of A at Birimingham	Dr. Joseph Barney	Melissa Garner	Dr. Ashita Tolwani
9	Memorial Sloan Kettering Cancer Center	Dr. Steve Pastores	Natalie Kostelecky	Dr. Sheron Latcha
10	University of Nebraska Medical Center	Dr. Andre Kalil	Kimberly Gallion-Exum	Dr. Marius Florescu
11	UPH Hospital - Univeristy of Arizona	Dr. Harold Szerlip	Ginny Stasinki Lisa Slayton Loveland Steven Triponey	Dr. Machaiah Madhrira
12	Baystate Medical Center	Dr. Mark Tidswell	Lori-Ann Kozikowski Judith Scott	Dr. Benjamin Freda
13	VCU Medical Center	Dr. Kyle Gunnerson	Tamara Ponton	Dr. Daniel Carl
16	University of Iowa	Dr. Gregory Schmidt	Andrew Potts	Dr. Manish Suneja
19	Easter Idaho Medical Center	Dr. Kenneth Krell	Amy Thornley	Dr. Micahel Haderlie
20	UCSD Medical Center	Dr. Ravindra Mehta	Sara Ortiz Marcela Zhou Huang	Dr. Danuta Trzebinska
21	Washington University Hospital	Dr. Anitha Vijayan	Marta Santos Stacy Schrader	Dr. Tingting Li
22	Thomas Jefferson University Hospital	Dr. Michael Baram	Susan Eberwine	Dr. Won Kook Han
23A	SERRI - Memorial	Dr. James Tumlin	Koumal Culver (A)	Dr. Claude Galphin
23B	SERRI - Erlanger		Jill Metcalf (B)	
25	Orlando Regional Medical Center	Dr. Edgar Jimenez	Valerie Danesh	Dr. Jeffrey Cohen
26	University of Alberta Hospital	Dr. Sean Bagshaw	Samantha Taylor	Dr. Noel Gibney

EUPHRATES TRIAL SITES

Site #	Site Name	Principal Investigator	Lead Coordinator	Nephrologist
27	Mercy St. Vincent Medical Center	Dr. Luis Jaregui	Dee Tilley	Dr. Bikram Johar
28	Sharp Memorial Hospital	Dr. David Wilms	Sharlee Middlebrook	Dr. Bijal Patel
29A	Memorial Health System - Central	Dr. Ronald Rains	Kathy Schafer	Dr. Mark Cook
29B	Memorial Health System - North			
30	Sunnybrook Health Sciences Center	Dr. Neil Adhikari	Nicole Marinoff	Dr. Michelle Hladunewich
			Jane Wang	
31	Kentucky Lung and Sleep Clinic	Dr. Firas Koura	Lori Akers	Dr. Jyotin Chandarana
			Margie Coots	
32	Christiana Hospital	Dr. Gerard Fulda	John Getchell	Dr. William Dahms
33	OSF Saint Francis Medical Center	Dr. William Tillis	Ashley Scott	Dr. Samer Sader
34A	UTHSCSA	Dr. Antonio Anzueto	Tim Houlihan	Dr. Paolo Fanti
34B	STVHCS			
25	Orlando Regional Medical Center	Dr. Edgar Jimenez	Valerie Danesh	Dr. Jeffrey Cohen
26	University of Alberta Hospital	Dr. Sean Bagshaw	Samantha Taylor	Dr. Noel Gibney
				Dr. Adam Romanovsky
27	Mercy St. Vincent Medical Center	Dr. Luis Jaregui	Dee Tilley	Dr. Bikram Johar
28	Sharp Memorial Hospital	Dr. David Wilms	Sharlee Middlebrook	Dr. Bijal Patel
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29B	Memorial Health System - North			
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			Jane Wang	
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			Margie Coots	
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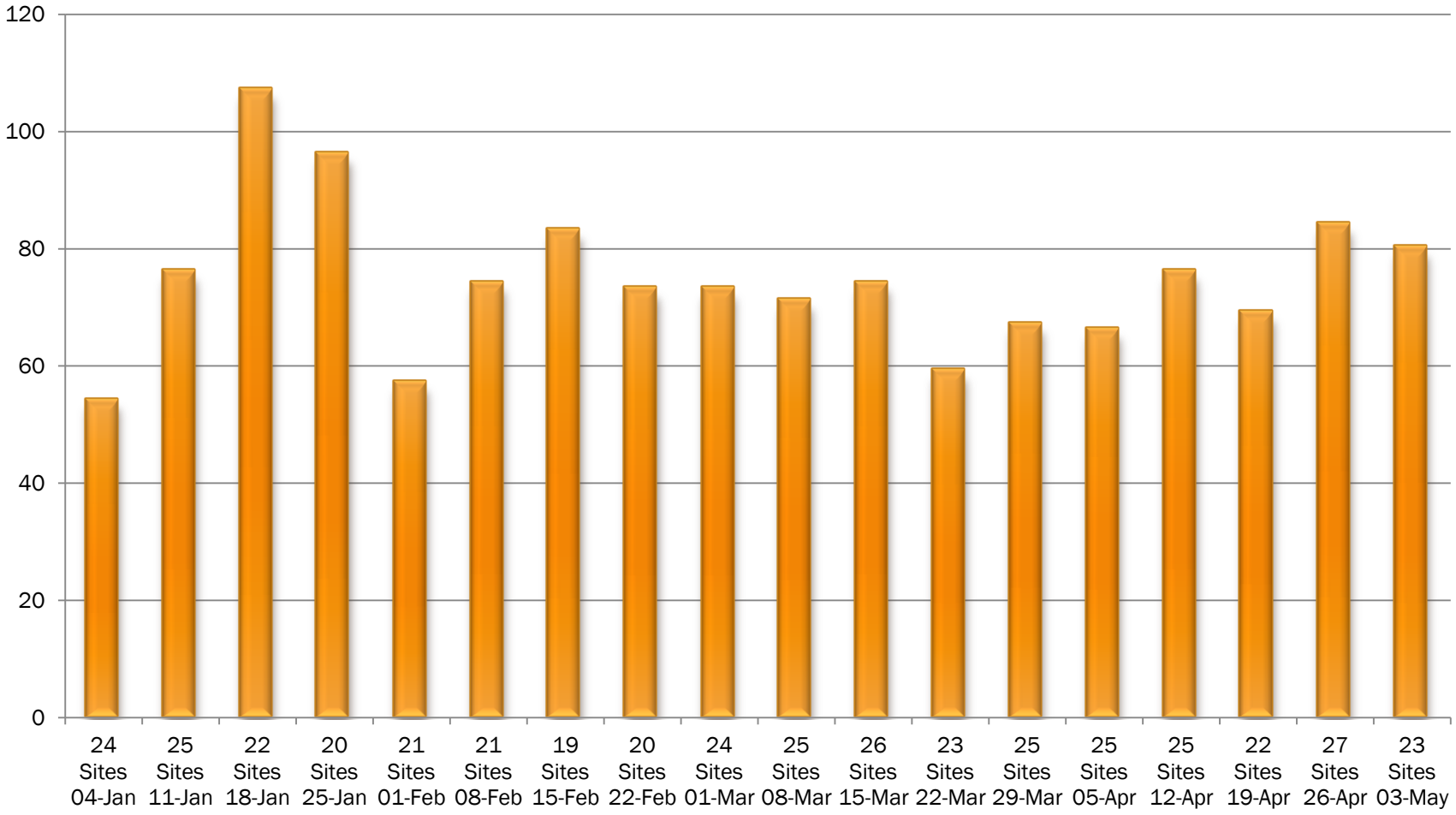
33	OSF Saint Francis Medical Center	Dr. William Tillis	Ashley Scott	Dr. Samer Sader
34A	UTHSCSA	Dr. Antonio Anzueto	Tim Houlihan	Dr. Paolo Fanti
34B	STVHCS			
35A	Ottawa Hospital - General	Dr. Lauralyn McIntyre	irene Watpool (A)	Dr. Kevin Burns
			Rebecca Porteous (A)	
35B	Ottawa Hospital - Civic		Tracy McArdle (B)	

EUPHRATES TRIAL SITES

Site #	Site Name	Principal Investigator	Lead Coordinator	Nephrologist
36	Rush University	Dr. Robert Balk	Joyce Brown	Dr. Roger Rodbey
37	Riverside Methodist	Dr. Edward Cordasco	Jennifer Botte	Dr. James Lewis
38	UMPC	Dr. Ivonne Daly	Marcy Lindley	Dr. Jose Bernardo
39	Miami VA	Dr. Roland Schein	Michael Hyre	Dr. Ivonne Schulman
40	West Suburban	Dr. Benjamin Margolis	Kelly Maple	Dr. George Naratadam
41	Massachusetts General	Dr. Wilfred Williams	Sandy Debronkart	
42	Mount Sinai	Dr. Roopa Kohli-Seth	Bridget Twohig	Dr. Benjamin/ Dr. Oropello/Dr. Manasia/ Dr. Bassily-Marcus/ Dr. Leibowitz
43	Lakeridge Health	Dr. Randy Wax	Stephanie Slemko	Dr. Andrew Steele
44	Royal Alexandra	Dr. Kutsogiannis	Patricia Thomspon	Dr. Darren Markland
45	IUCPQ	Dr. Francois Lellouche	Marie-Claude Ferland	Dr. Isabelle Plamondon
46	Cleveland Clinic	Dr. Sevag Demirjian/ Dr. Guzman	Rita Brienza	Dr. Sevag Demirjian
47	Dallas VA	Dr. Devasmita Dev	Lynne Roetzer	
48	Henry Ford Hospital	Dr. Emanuel Rivers	Anja (Kathrina) Jaehne	Dr. Balazs Szamosfalvi
49	Foothills Medical	Dr. Brent Winston	Christine Skinner	Dr. Jennifer McRae
	Saint Louis University	Dr. David Stoeckel	Kathryn Lindsay	
	UHN	Dr. Jeffrey Singh	Paulina Farias Andrea Matte	Dr. Robert Richardson
	Stanford University	Dr. Ronald Pearl	Alison Pepper	Dr. Richard Lafayette
	University of Mississipi Medical Center	Dr. Luis Juncos	Kathryn Roberson	
	East Carolina University	Dr. Brett Waibel	Frank Watkins	Dr. Graham Byrum
	George Washington	Dr. Mink Chawla	Christina Seneff	
	Mount Sinai (Toronto)	Dr. Stephan Lapinsky	Maedean Brown	
	Pittsburgh VA	Dr. Chris Brackney		
	McGill University	Dr. Sheldon Magder		

NUMBERS PRE-SCREENED WEEKLY TOTALS



EUPHRATES

PRE-SCREEN ACTIVITY

	Pre-Screen Activity: Week of 26 Apr 13 to 2 May 13																											
		01	05	07	09	11	12	13	16	19	20	21	23A	23B	25	26	27	28	29A	29B	31	33	34A	34B	35A	35B	37	45	Totals
	Number Pre-Screened	6	5	2	4	3	1	0	6	0	1	22	1	0	3	4	10	2	1	0	2	6	0	0	0	1	0	0	80
	Number Failing Pre-Screen	6	5	2	4	3	1	0	5	0	1	22	0	0	3	4	10	2	1	0	2	6	0	0	0	0	0	0	77
I2c	Vasopressors did not reach required dose					1			2			4			1		3				1	2							14
E4	End stage renal disease requiring dialysis		2	1								4				1					1								9
I2b	Vasopressors for > 30 hours	1	1						1		1	2					1												7
I3	IV fluid resuscitation		1						2			2					2												7
I6	New qualifying organ dysfunction is not present	1	1									1			1				1			2							7
E5	Clinical evidence for non-septic shock	1	1									4																	6
I2e	Vasopressor stopped prior to EAA consent	1	1									2			1														5
E8	Uncontrolled hemorrhage					1						2				1	1												5
E10b	PLT <30	1			1							2				1													5
E1b	Surrogate unavailable to obtain informed consent					1						2				1													4
E7	Acute MI in past 4 weeks											1					2	1											4
E2	Not committed to full medical support						1									1	1												3
E6	CPR chest compressions w/o return to communicative state		1									2																	3
E9	Major trauma within 36 hours of screening											2						1											3
E10a	WBC				2							1																	3
E17	Participating in another clinical trial				3																								3
I2a	Vasopressors for < 2 hours					2																							2
I4	No infection or IV antibiotics											1					1												2
E16b	H.I.T. history	1										1																	2
E1a	Patient/surrogate chose not to participate in the trial			1																									1
E16a	Heparin hypersensitivity																					1							1
E19O1	Life expectancy ? if live next 24 hours																					1							1
E19O1	moribund															1													1
I1	Age < 18																												0
E3	Unable to achieve or maintain a MAP ≥65 mm Hg																												0
E11	HIV infection and CD4																												0
E12	Subject baseline state is non-communicative																												0
E13	Extensive 3rd degree burns																												0
E14	Weight of < 35 kg (77 lbs)																												0
E15	Polymyxin B Hypersensitivity																												0
E18	Previously enrolled in this trial																												0

THE GOAL FOR 2013

- .25 patients/centre/month enrolled
- 45 to 50 sites enrolling
- 184 patients enrolled by end of 2013

The Statistical Plan (SAP)

- Determined method of end point analysis
- Analysed interim analysis statistical approach
- Planned interim analysis
- Determined methods for analysis of secondary endpoints
- Submitted SAP to the FDA - accepted

Statistical Analysis Plan

- Safety Assessment Analysis (1st Interim Analysis)
- After approximately 20% of the required population (76/360 treated subjects) have completed the 28-day post-treatment observation period or have died (or were withdrawn)
- No planned inferential statistics
- The Type I error rate for the final analysis will not be inflated
- No Type I error adjustment will be made due to this safety analysis

First Interim Analysis (n=76)

Role of the DSMB: (1) ensure safety of participants (2) protect validity of trial results

EUPHRATES DSMB:

- **Dr. J. Kellum; Dr. B. Spilker (Chair); Dr. S. Opal; Dr. R. Wald; Dr. C. Xiong (Statistician)**

- *"The results from the first interim safety analysis by the DSMB state that there are no safety issues to date concerning the application of the Toraymyxin cartridge to patients in the EUPHRATES trial. In addition, the results state that the EUPHRATES clinical protocol appears to be defining the correct target patient population for this study."*

Statistical Analysis Plan

- Efficacy Assessment Analysis (2nd Interim Analysis)
- After ~ 50% treated subjects, have completed the 28-day period or died/withdrawn
- O'Brien-Fleming approach is used and a p-value of less than 0.005 is required to successfully stop the trial, due to efficacy results
- O-Brien Fleming Approach is used to address the Type I error rate adjustment to protect the trial-wise Type I error at the final analysis.

Statistical Analysis Plan

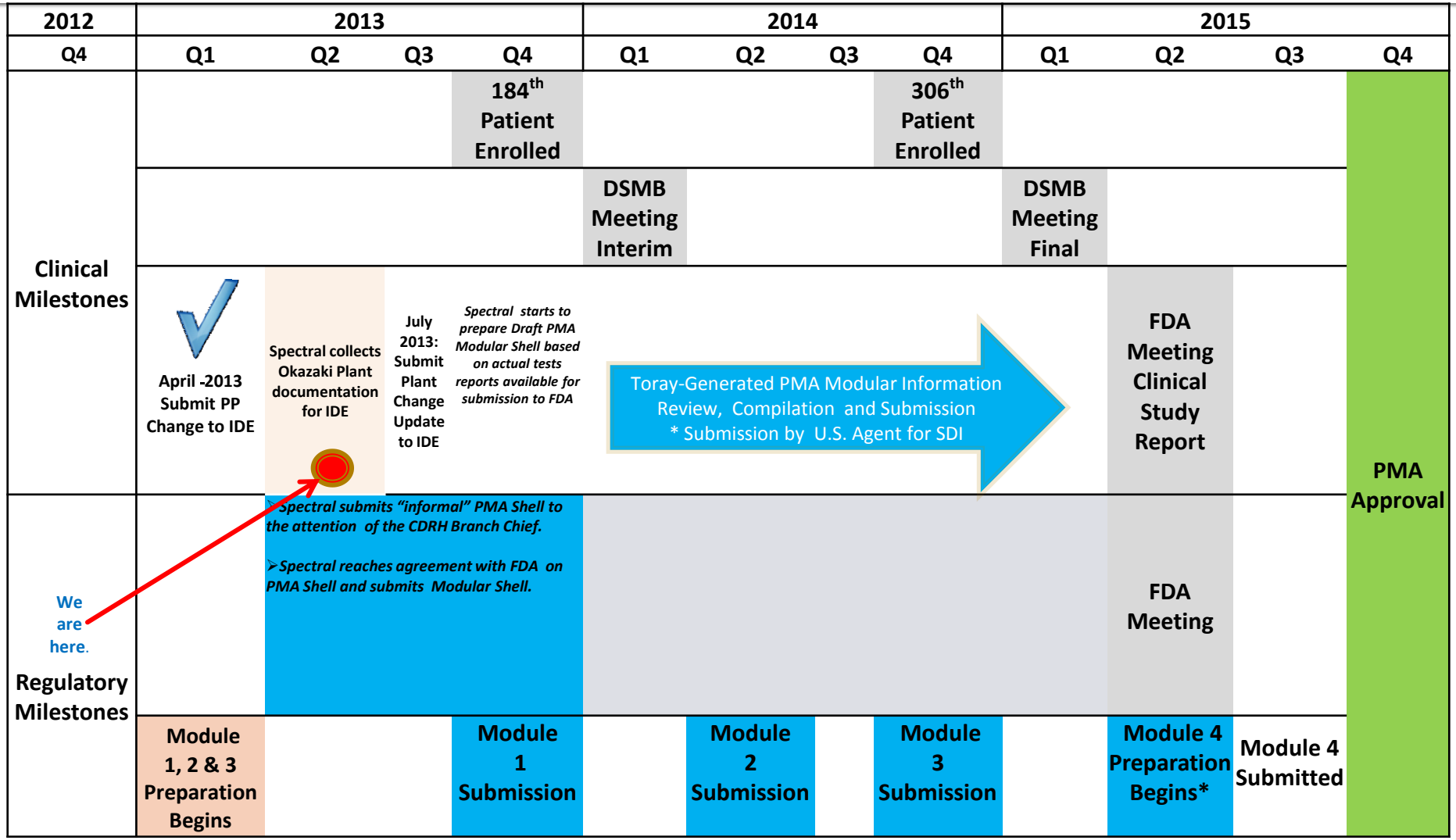
- Final Analysis once all subjects have completed the study
- For the Primary Endpoint: Fisher's Exact test

  (if the number of events in any cell is less than 5)

Statistical Analysis Plan

- Continuous data summaries will include: Number of observations, mean, standard deviation, median, and minimum and maximum values
- Analysis of Covariance (ANCOVA) OR Mixed Model
- Categorical data summaries will include: Frequency counts and percentages
- Fishers exact test or chi-square test will be used
- Time-dependent data: Kaplan Meier methods will be used to analyze time dependent data and to depict the time to event data.

Toraymyxin (PMX-20R) Master PMA Schedule



What is Partnering?

- **Business Partnering** is "the development of successful, long term, strategic relationships between customers and suppliers, based on achieving best practice and sustainable competitive advantage"(Lendrum, 1997).

Preparations for Partnering: EAA™

- Increase the awareness and commercial potential for EAA™ diagnostic
  - 5 studies ongoing, 2 recently completed and 5 IRB approved and soon to be underway
  - 10 papers published, plus many presentations and abstracts
- Prepare for scale up of manufacturing
  - Source and qualify large quantities of raw materials
  - Trehalose, Zymosan and IgM (A5)

Publications on EAA™

- Prognostic value of endotoxin activity assay in patients with severe sepsis after cardiac surgery.
  Journal of Inflammation, March 2013, 10:8
- Markers of intestinal injury are associated with endotoxemia in successfully resuscitated patients.
  Resuscitation Volume 84, Issue 1 , Pages 60-65, January 2013
- Bench-to-bedside review: Clinical experience with the endotoxin activity assay.
  Critical Care 2012, 16:248, December 2012
- Increased endotoxin activity is associated with clinical deterioration in moderate-severity emergency department sepsis patients: a pilot study
  Critical Care 2012, Volume 16. Supp. 3, Sepsis 2012, November 2012
- Impact of endotoxin measured by an endotoxin activity assay during liver transplantation
  Journal of Surgical Research, May 2012
- Combining intermediate levels of the Endotoxin Activity Assay (EAA) with other biomarkers in the assessment of patients with sepsis: results of an observational study
  Critical Care 2012, 16:R88
- Clinical usefulness of measuring endotoxin activity on ICU admission
  Critical Care 2012, 16(Suppl 1):P34
- Maximal Chemiluminescent Intensity in Response to Lipopolysaccharide Assessed by Endotoxin Activity Assay on Admission Day Predicts Mortality in Patients With Sepsis
  Critical Care Medicine, ahead of print (March/April 2013?)
- New biomarker panel of plasma neutrophil gelatinase–associated lipocalin and endotoxin activity assay for detecting sepsis in acute kidney injury
  Journal of Critical Care, March 2013
- Sepsis and AKI in ICU Patients: The Role of Plasma Biomarkers
  Critical Care Research and Practice, February 2012
- *Waiting for publication*
- ENDOTOXIN ACTIVITY LEVELS AS A PREDICTION TOOL FOR RISK OF DETERIORATION IN PATIENTS WITH SEPSIS NOT ADMITTED TO THE ICU
  Journal of Critical Care

Preparations for Partnering: Toraymyxin

- Increase awareness of efficacy/commercial presence of Toraymyxin
  - Multiple studies ongoing and reported
  - Toray and Spectral cooperating commercially in 9 countries and exploring opportunities in 3 more countries
- Toraymyxin Manufacturing
  - Large quantities of raw material sourced
  - New manufacturing plant built
  - Manufacturing to be compliant with FDA standards

Publications on Toraymyxin

- **Favorable outcome with hemoperfusion of polymyxin B-immobilized fiber column for rapidly progressive interstitial pneumonia associated with clinically amyopathic dermatomyositis: report of three cases**
  Modern Rheumatology, October 2012
- **Nephrologists and Sepsis: The Promise of Extracorporeal Therapy**
  Nephrology Times, August 2012
- **Early use of polymyxin B in sepsis**
  Journal of Italian Nephrology **(NCBI Abstract, original publication in Italian)**
- **Polymyxin B hemoperfusion (PMX-F) for severe sepsis and septic shock**
  Japanese Journal of Critical Care Medicine**.** Abstract only - original article in Japanese
- **Safety of Polymyxin-B–based Hemoperfusion in Kidney and Liver Transplant Recipients**
  Transplantation Proceedings, Sept 2012
- **Time to Initiation of Treatment with Polymyxin B Cartridge Hemoperfusion in Septic Shock Patients**
  Blood Purification, June 2012

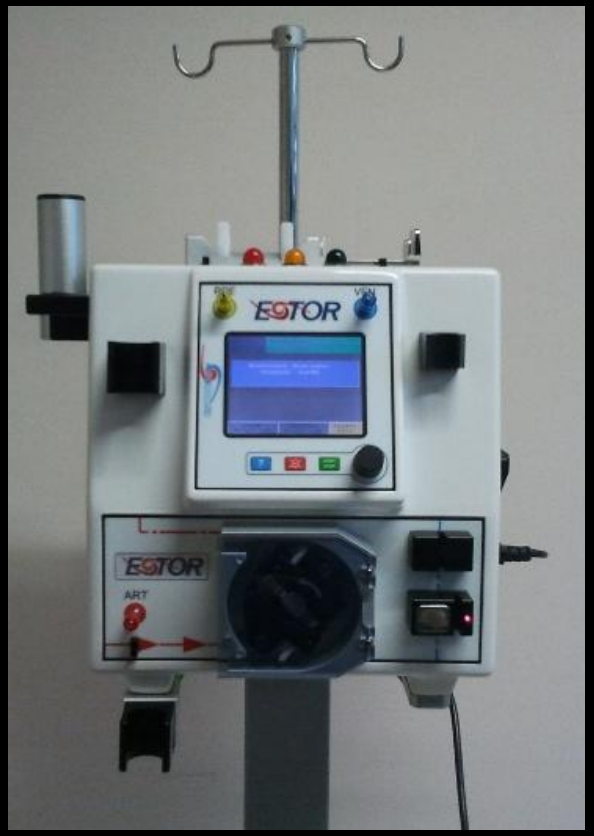
Accepted and waiting for publication

- **Blood Purification and mortality in sepsis**
  John Kellum et al
  Critical Care Medicine

EstorFLOW® is a system designed for optimal hemoperfusion during the removal of endotoxin, through the joint application of the Toraymyxin® cartridge.

is designed in order to make PMX procedure:

- User Friendly
- Simple
- Safe



VP Sales and Marketing

Prior to joining Spectral, Dr. Guadagni spent 10 years at ESTOR S.P.A where he was the company's sales and marketing director, and scientific consultant for Toraymyxin. ESTOR is a Milano-based company specialized in the production, promotion and sale of advanced biomedical devices in the areas of dialysis, intensive care and hemodynamics.

As ESTOR's sales and marketing director, Dr. Guadagni managed an 18-person sales and marketing team that focussed on selling and marketing Dialysis products on the Italian Market, as well as intensive care product such as Toraymyxin, EAA™ and proLUNG in Italy, Switzerland and Austria where the sales of EAA™ and Toraymyxin have grown annually.

Dr. Guadagni has a PhD in bioengineering and a master's degree in mechanical engineering, both from Politecnico di Milano University in Italy.

What are the characteristics we would *like to see* in a partner?

- A knowledgeable sales/marketing group with proven access to critical care decision makers
- Sizeable market cap and willingness to fund start up marketing and educational promotion
- Able to market both diagnostic and therapeutic devices
- Great regional strength in North America and interest in other jurisdictions such as Europe

What are the characteristics we *don't want to see* in a partner?

- Commodity based business competing only on price
- Companies with only experience in selling to the Laboratory or solely to infectious disease doctors
- Large company where our product is not a priority

GOALS FOR THIS YEAR

- Reach patient enrolment for 2nd Interim Analysis
- Manage the trial within budget and at the highest level of quality
- Increase commercialization activities
- Move closer to partnering
- Increase shareholder value

Infection and Sepsis-Related Mortality Hotspots Identified Across the U.S.

May 15, 2013 — In the past, researchers have sought to determine the geographic distribution of many life-threatening conditions, including stroke and cardiac arrest. Now, researchers at the Perelman School of Medicine at the University of Pennsylvania have created the first U.S. map that pinpoints hotspots for infection and severe sepsis related-deaths -- with notable clusters located in the Midwest, mid-Atlantic, and the South. The research is a critical first step in helping to determine which areas of the country require vital public health resources to fight these deadly diseases.

The new research will be presented at the annual meeting of Society for Academic Emergency Medicine in Atlanta, Ga.

"Infection-related deaths are a leading cause of morbidity and mortality in the U.S., affecting over 1 million people a year, and costing $17 billion annually," said lead study author David Gaieski, MD, an associate professor of Emergency Medicine at Penn. "And while our understanding of the causes of infection-related death rates has improved, we are still struggling to prevent these diseases and identify individuals who are most susceptible. We need to be able to pinpoint the geographic distribution of infection-related death rates in order to further study how and why these infections are happening in these areas and the best methods to prevent these deaths."

Sepsis is the tenth leading cause of death in the United States. With an estimated 750,000 cases annually and a nearly 40 percent mortality rate, severe sepsis is also one of the most common causes of death in hospital critical care units.

To better understand what areas of the country are most at risk for severe sepsis and other infection-related deaths, the research team collected U.S. county death data from the 2010 Multiple Cause of Death data files (compiled by the National Center for Health Statistics) and combined it with 2010 Area Resource File demographic data for a comprehensive view of national variations. The authors note that previous research had only been able to identify potential trends on a state level.

Infection-related deaths were identified using ICD-10 primary cause of death codes for infection and severe sepsis. "Hotspots" were defined as regions where the infection death rate was significantly higher than the national mean and surrounding counties. The analysis revealed four hotspots: 1) two regions that had three times the national mean of infection-related deaths located across the Midwest and mid-Atlantic and 2) two regions that had four times the national death rate from severe sepsis, located in the South and mid-Atlantic.

In addition to the hotspots, the research team also identified one "coolspot" cluster, an area that had disproportionately low rates of deaths caused by these infections. The coolspot cluster consisted of 157 counties located across the Southwest and Mountain states. The research team notes that these "coolspot" counties might yield important insights as well, including particular screening and treatment protocols that may be in place in these areas.

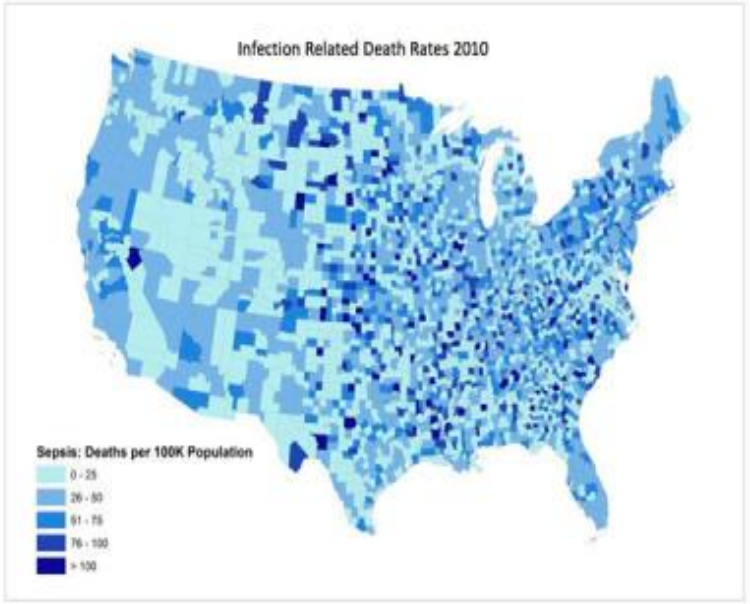
"This analysis may help target focused geographical interventions to improve the dissemination and implementation of evidence-based care," said senior study author Brendan G. Carr, MD, MA, assistant professor of Emergency Medicine, Surgery, & Epidemiology at Penn. "Further study is required to clarify the geographic variability we observed, but we believe this new resource will be a helpful tool for researchers and public health officials."

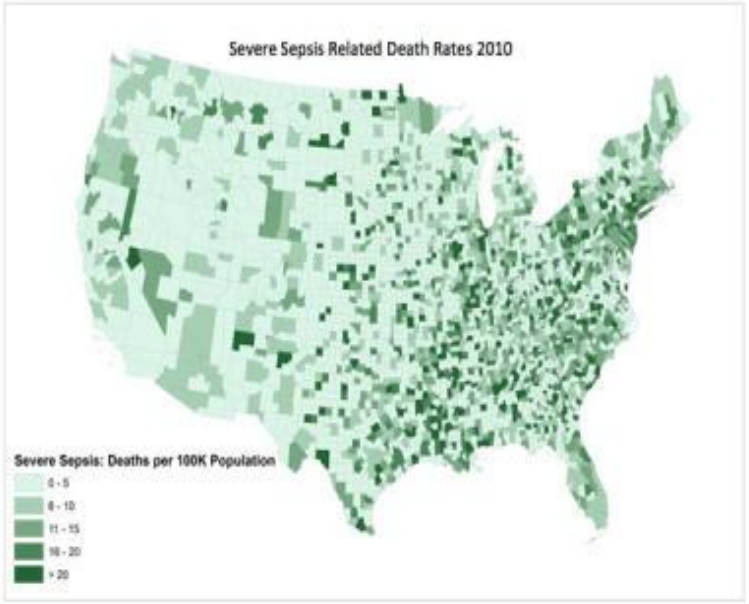
Additional authors from Penn include Anish Agarwal, MD, MPH, Catherine S. Wolff, Douglas Wiebe, PhD, and Mark E. Mikkelsen, MD.

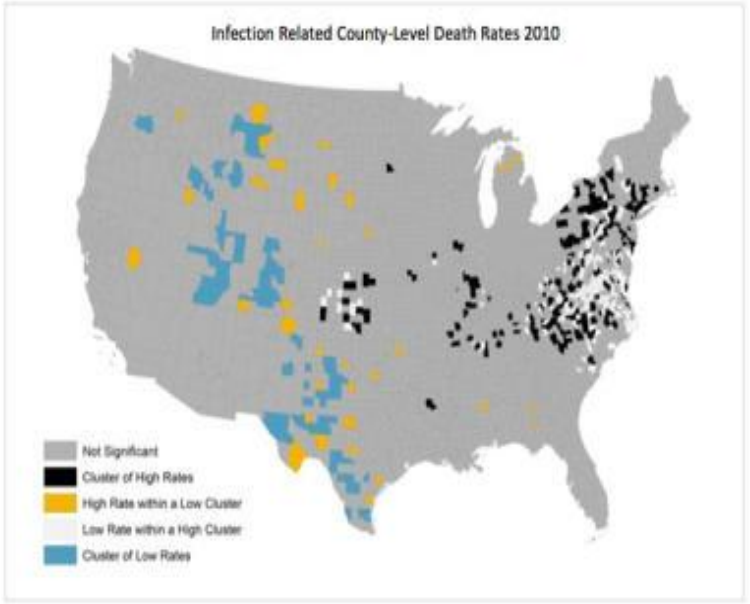
Story Source:

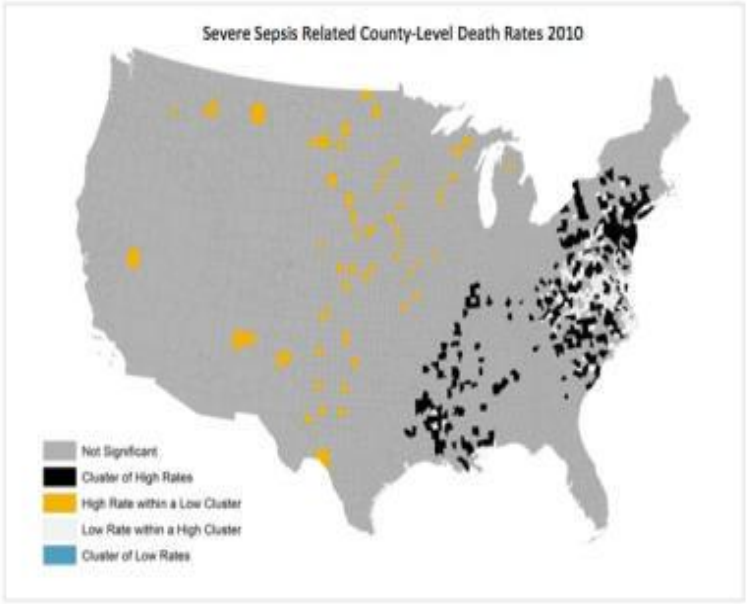
The above story is reprinted from materials provided by **Perelman School of Medicine at the University of Pennsylvania**.

Note: Materials may be edited for content and length. For further information, please contact the source cited above.


Infection Related Death Rates 2010
Sepsis: Deaths per 100K Population
0 - 25
26 - 50
51 - 75
76 - 100
> 100


Severe Sepsis Related Death Rates 2010
Severe Sepsis: Deaths per 100K Population
0 - 5
6 - 10
11 - 15
16 - 20
> 20


Infection Related County-Level Death Rates 2010
Not Significant
Cluster of High Rates
High Rate within a Low Cluster
Low Rate within a High Cluster
Cluster of Low Rates


Severe Sepsis Related County-Level Death Rates 2010
Not Significant
Cluster of High Rates
High Rate within a Low Cluster
Low Rate within a High Cluster
Cluster of Low Rates