



*Leading Development of  
Novel Anti-Infective Products  
in the Era of Increasing  
Bacterial Resistance*

# Forward Looking Statements

This presentation contains certain statements that constitute forward-looking statements within the meaning of the federal securities laws. Statements that are not historical facts, including statements about our beliefs and expectations, are forward-looking statements. These statements are not guarantees of future performance and involve risks, uncertainties and assumptions that are difficult to predict. The forward looking statements in this presentation include statements about our business, including commercialization plans and potential markets for our products and product candidates, clinical trials, potential indications for our product candidates, development timelines, regulatory timelines and future events that have not yet occurred. Pharmaceutical and medical device development inherently involves significant risks and uncertainties, including the risks outlined in “Risk Factors” in our Annual Report on Form 10-K filed with the Securities and Exchange Commission and in “Risk Factors” in our Quarterly Reports on Form 10-Q filed with the Securities and Exchange Commission. Our actual results may differ materially from our expectations due to these risks and uncertainties, including, but not limited to, our dependence on the success of our lead product candidate Neutrolin, and factors relating to commercialization and regulatory approval thereof; unpredictability of the size of the markets for, and market acceptance of Neutrolin; the cost, timing and results of the ongoing and planned Phase 3 trials for Neutrolin in the U.S.; ability to raise sufficient capital; our ability to identify and enter into strategic transactions; intellectual property protection; retaining our stock’s listing on the NYSE MKT; research and development activities; competition; industry environment, and other matters. Any forward-looking statements included in this presentation are based on information available to us on the date of this presentation. We undertake no obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

# Neutrolin<sup>®</sup> is Designed to Protect Patients and Hospitals *Keeps Sick Patients From Getting Sicker*

## Catheter-Related Blood Stream Infections (**CRBSI**)

#1 cause of hospital-acquired bacteremia  
in critically ill patients

- 250,000 infections / year in the U.S.<sup>1</sup>
- \$30,000-\$50,000+ / infection<sup>2</sup>

Extensive morbidity and mortality

- 20-25% mortality (U.S.)<sup>3</sup>
- Prolong hospital stays<sup>4</sup>

## Neutrolin<sup>®</sup>

Non-antibiotic anti-infective solution

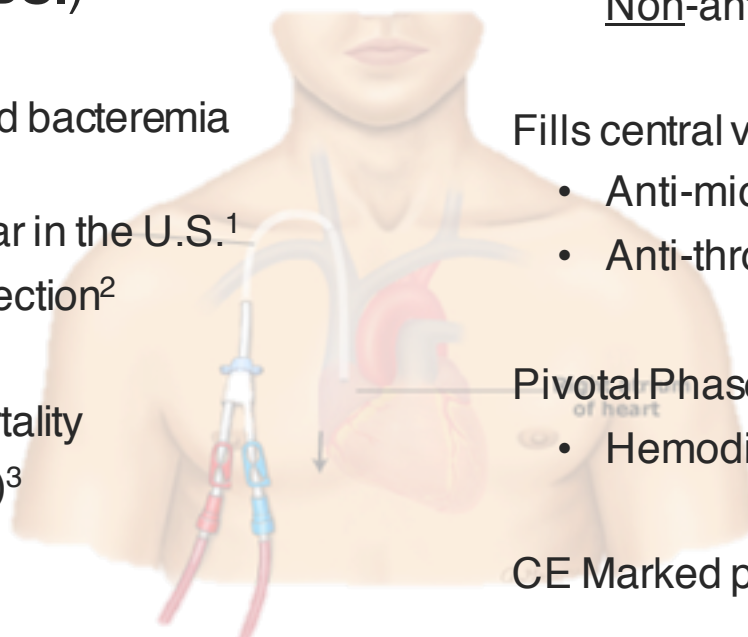
Fills central venous catheter between uses:

- Anti-microbial: **Prevents** CRBSI
- Anti-thrombotic: **Prevents** blood clots

Pivotal Phase 3 study ongoing in U.S.

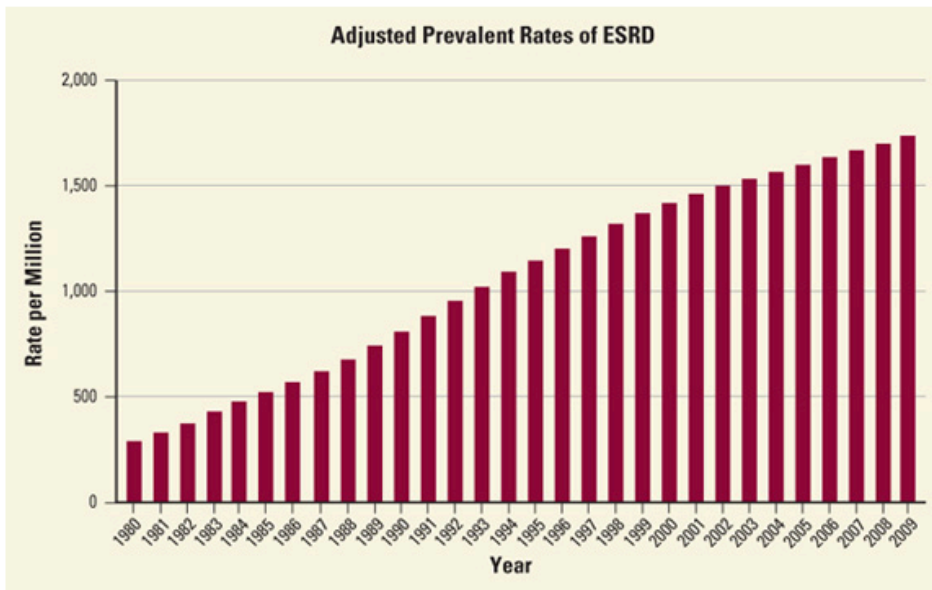
- Hemodialysis patients

CE Marked product in European Union

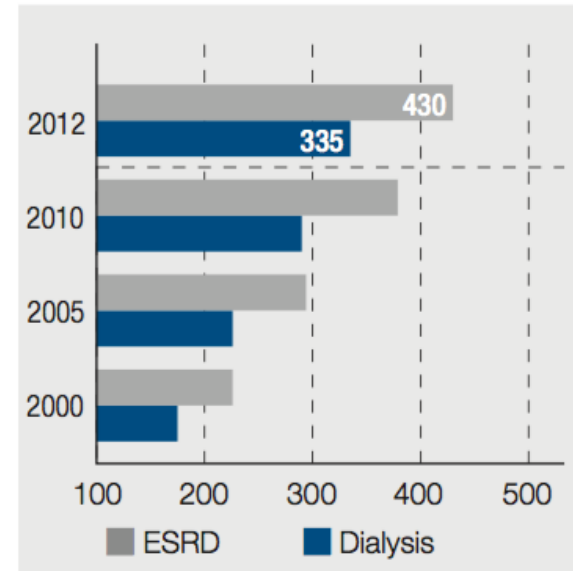


1. Soufir L, Timsit JF, Mahe C, Carlet J, Regnier B, Chevret S. Attributable morbidity and mortality of catheter-related septicemia in critically ill patients: a matched, risk-adjusted, cohort study. *Infect Control Hosp Epidemiol*. 1999;20:396-401.
2. Deliberato R, Marra A, Correa T. Catheter Related Bloodstream Infection (CR-BSI) in ICU Patients: Making the Decision to Remove or Not to Remove the Central Venous Catheter. *VCU Scholars Compass*. 2012
3. Brun-Buisson C. New technologies and infection control practices to prevent intravascular catheter-related infections. *Am J Respir Crit Care Med* 2001; 164: 1557-8
4. Brunelli, S, et al. Clinical and economic burden of bloodstream infections in critical care patients with central venous catheters. *Journal of Critical Care*, Volume 35, 69 - 74

# Growing Hemodialysis Patient Population = Increased CRBSI Burden to Global Healthcare System



*Development of global ESRD and dialysis prevalence values since 2000 (patients per million population)*



National Institute of Health, National Institute of Diabetes, Digestive, and Kidney Diseases:  
<http://www.niddk.nih.gov/health-information/health-statistics/Pages/kidney-disease-statistics-united-states.aspx>

ESRD Patients in 2012, a Global Perspective; Fresenius Medical Care Deutschland GmbH:  
<http://bit.ly/29echO5>

# Neutrolin<sup>®</sup>: Non-antibiotic Anti-Infective to Prevent CRBSI

Neutrolin<sup>®</sup>

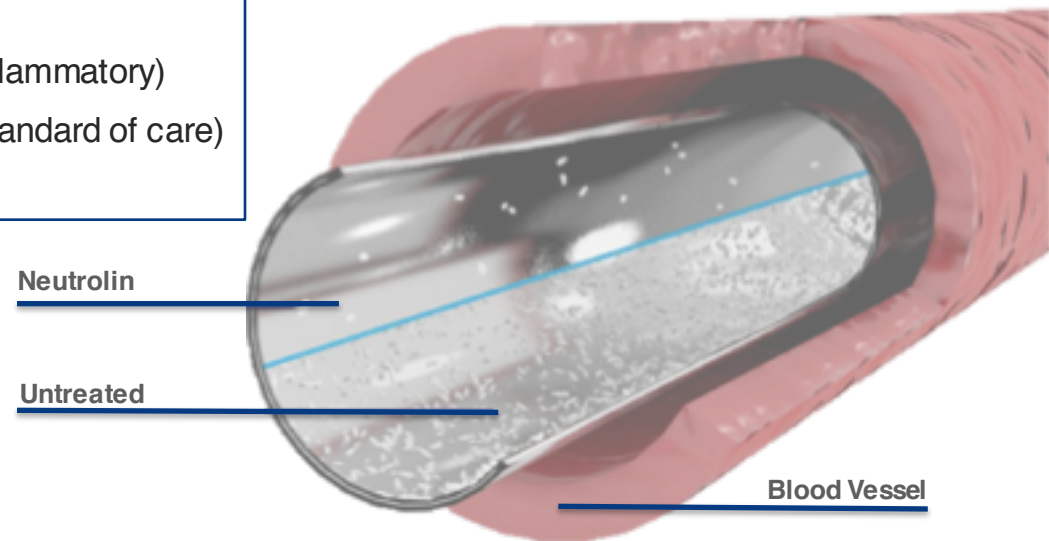


Proprietary formulation:

- **Taurolidine** (anti-infective, anti-inflammatory)
- **Heparin** (anti-coagulant; current standard of care)
- **Citrate** (buffer)

**Prevents Microbial Colonization and Biofilm Formation Inside Catheter**

**Reduces Risk of Bloodstream Infection**

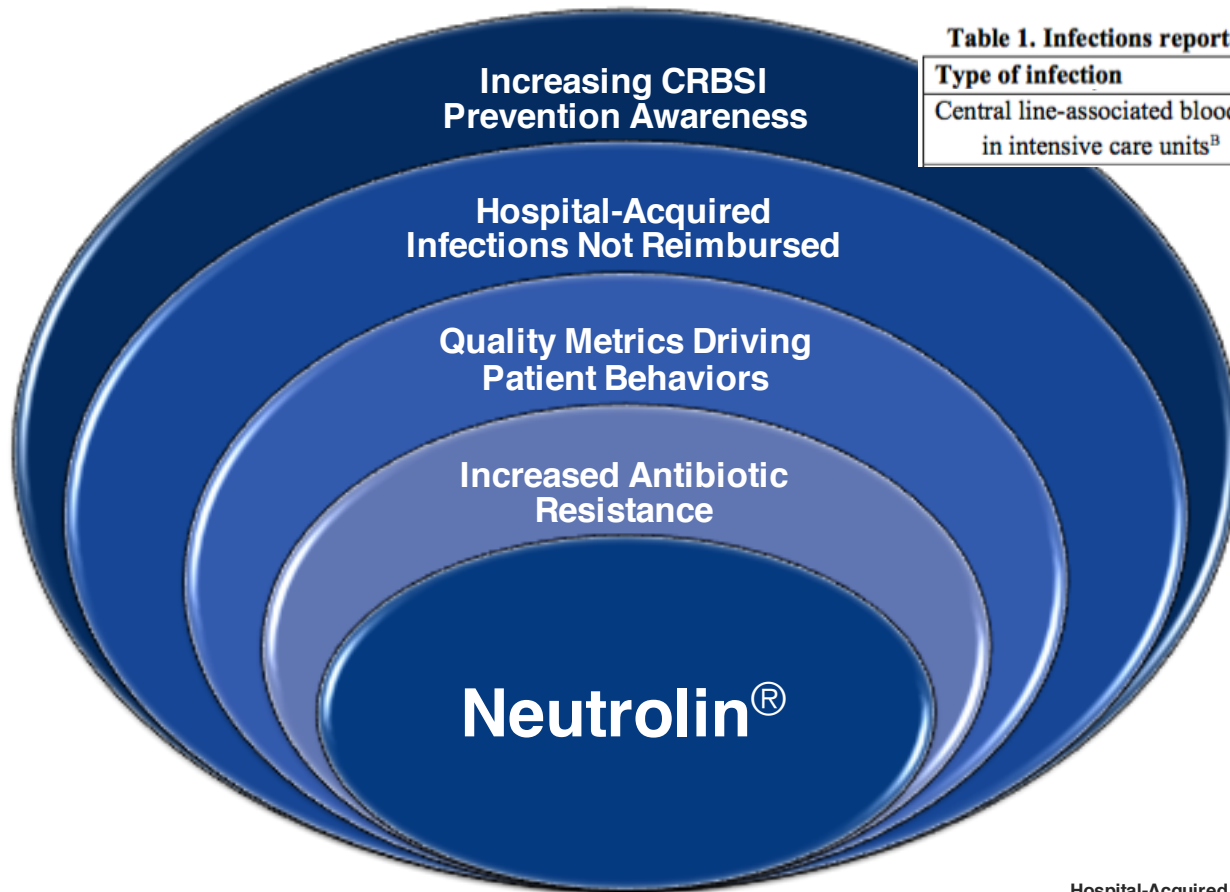


## Non-antibiotic Taurolidine:

- Broadly active against bacteria, including drug-resistant MRSA, VISA, VRSA, ORSA and VRE
- Kills microbes by disrupting bacterial cell wall; Blocks cell adhesion by inhibiting bacterial fimbriae
- **No microbial resistance developed to date**

Source: Caruso F, Darnowski JW, Opazo C, Goldberg A, Kishore N, et al. (2010) Taurolidine Antiadhesive Properties on Interaction with *E. coli*; Its Transformation in Biological Environment and Interaction with Bacteria Cell Wall. PLoS ONE 5(1): e8927. doi:10.1371/journal.pone.0008927

# Multiple Factors Expected to Drive Neutrolin<sup>®</sup> Adoption



**Table 1. Infections reported by New York State hospitals in 2014**

Type of infection	Number	Rate
Central line-associated bloodstream infections (CLABSIs) in intensive care units <sup>B</sup>	546	0.9/1,000 line days

		Blood Stream Infections	
		ICU CLABSI	
Hospital	Yr	Observed/ Predicted	SIR
Bellevue Hospital	13	6/ 6.6	0.91
	14	6/ 7.5	0.80
Jacobi Medical	13	5/ 4.2	1.19
	14	3/ 3.6	0.84
Jamaica Hospital	13	15/ 4.9	^3.04
	14	2/ 3.5	0.57
NYP-Weill Cornell	13	34/23.9	1.42
	14	21/17.6	1.19
NYU Medical Center	13	6/11.6	0.52
	14	8/ 9.9	0.81

Hospital-Acquired Infections, New York State (2014) New York State Department of Health, Albany, NY

# U.S. Clinical Strategy

**Approval Pathway:** Designated a therapeutic

- Granted FDA Fast Track
- Qualified Infectious Disease Product (QIDP)

**10.5 years  
Market Exclusivity**

## Phase 3 “**LOCK-IT**” Program (Catheter **LOCK** Solution **I**nvestigational **T**rial)

Ongoing: **LOCK-IT 100**: Currently enrolling hemodialysis patients

- 4Qtr 2016: Blinded interim safety analysis
- 2Qtr 2017: Complete patient enrollment
- Year-end 2017: Report top-line data

Planned: **LOCK-IT 200**: Oncology patients receiving IV parenteral nutrition, chemotherapy and hydration via catheter

- 4Qtr 2016: Anticipate meeting with FDA to finalize protocol

**Post-market Phase 4 studies:** ICU/CCU patients

# LOCK-IT 100: Preventing CRBSI in Hemodialysis Patients

## Study Design

- Phase 3, multicenter, double-blind, randomized (1:1), active control (heparin)
- 632 hemodialysis patients on a catheter for end stage renal disease
  - Currently enrolling

## Primary Endpoint

Time to occurrence of CRBSI in patients using Neutrolin vs. heparin as a catheter lock solution

## Key Secondary Endpoints

- Catheter patency
- Catheter removal
- Pharmacoeconomic analysis



# Neutrolin Clinically Validated in Real World Setting

## Neutrolin Usage Monitoring Program (NUMP) – Open Label Study Post-market observational study conducted in Germany

<b>Complication</b> (per 1000 catheter days)	<b>Historical Benchmark</b>	<b>Neutrolin®</b>	<b>% Reduction</b>
<b>Infection</b>	<b>3.5<sup>1</sup></b>	<b>0.142</b>	<b>96%</b>
<b>Thrombosis</b>	<b>2.5<sup>2,3</sup></b>	<b>0.085</b>	<b>96.7%</b>

n=202 patients, representing 36,083 hemodialysis catheter days

- Positive results consistent with prior clinical studies
- Data accumulated from NUMP registry add support to U.S. NDA filing

1.CDC Guidelines for the Prevention of Intravascular Catheter Related Infections; O`Grady et al., 2011. 2. Morris P, Knechtle SJ. *Kidney Transplantation - Principles and Practice*. Saunders, 2013. Print..3. Napalkov P, Felici DM, Chu LK, Jacobs JR, Begelman SM. [Incidence of catheter-related complications in patients with central venous or hemodialysis catheters: a health care claims database analysis.](#)

# Prior Studies

Study	Number of Patients	Patient Type	Avg. Duration (Days)	% Infection Reduction vs. Control
1 (2003)	20 pts Taurolidine (T) 30 pts Heparin (H)	Hemodialysis	90	50%
2 (2004)	37 catheters T 39 catheters H*	Hemodialysis	158	100%
3 (2001)	76 pts T	Hemodialysis	250	96%
4 (2010)	16 pts T 14 pts H	Adult Home Parenteral Nutrition	641	91.24%
5 (2012)	9 pts	Adult Home Parenteral Nutrition	1000	100%
6 (2012)	19 pts	Pediatric Home Parenteral Nutrition	1000	87.2%
7 (2013)	64 catheters T 65 catheters H	Pediatric Oncology Patients	1000	71.4%

\*From 58 patients

1. **Allon M** Clin Infect Dis (2003) 36 (12):1539-44, 2. **Bejtes** Nephrol Dial Transplant (2004) 19:1546-1551, 3. **Sodemann K et al** Poster: ASN 2001, 4. **Bisseling, T. M., M. C. Willems, et al.** (2010) Clin Nutr 29(4): 464-8, 5. **Al-Amin, A. H., J. Sarveswaran, et al.** (2013). J Vasc Access 0(0): 0., 6. **Chu, H. P., J. Brind, et al.** (2012). J Pediatr Gastroenterol Nutr 55(4): 403-7, 7. **Handrup, M. M., J. K. Moller, et al.** (2013). Pediatr Blood Cancer 60(8): 1292-8

# U.S. Market Potential is Substantial; Driven by Catheter Days

Neutrolin®	Patients	Catheter Days	Vials per Catheter Day	Total Units
Hemodialysis	468,000	127,000,000	0.5	55,880,000
			<b>Cartridges/Vials per Catheter Day</b>	
Oncology/TPN	7,740,000	90,000,000	3	270,000,000
ICU	5,700,000	28,500,000	5	142,500,000

**468,380,000 / year**

**Catheter Population and Related Infection Rates are Significant**

Hemodialysis: National Kidney Foundation, The Facts About Chronic Kidney Disease. New York, NY, 2012. ; U.S. Renal Data System, USRDS 2011 Annual Data Report: Atlas of Chronic Kidney Disease and End Stage Renal Disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2011 and CorMedix estimates  
 Oncology: American Cancer Society, Cancer Facts and Statistics. <http://www.cancer.org/research/cancerfactsstatistics/>. Accessed on April 1, 2015 and CorMedix estimates  
 Intensive Care Units: Society of Critical Care Medicine. Critical Care Statistics. <http://www.sccm.org/Communications/Pages/CriticalCareStats.aspx>. Accessed on April 10, 2015 and CorMedix estimates



# Taurolidine's Anti-infective/Anti-Inflammatory Properties Could Add Value to Medical Devices

Actively seeking partnership/co-development opportunities

Product (market)	2015 Market Size (forecasted, \$MM)	2018 Market Size (forecasted, \$MM)	Projected CAGR
<b>Sutures</b> (Global)	\$3,516	\$3,962	4%
<b>Topicals</b> (U.S.)	903	1,029	5%
<b>Viscosupplementation</b> (U.S.)	776	984	9%
<b>Nanofiber webs</b> (U.S.)*	246	474	25%

\*Recently entered into research collaboration with Luna Innovations

# Novel Taurolidine-based Cancer Therapy

## Taurolidine and Cancer

- Known to inhibit a variety of human cancer cell growth *in vitro*; Shown recently to specifically inhibit neuroblastoma cell lines<sup>1</sup>
- Significantly enhances activity of cytotoxic drugs against neuroblastoma<sup>2</sup>

## May 2016: Exclusive research licenses to NanoProteagen's NanoPro™ technology

- Delivering combination therapy: CRMD-005 plus vincristine (marketed as Oncovin®)
- Currently testing feasibility, with option to obtain exclusive worldwide license

## Initial Target: Pediatric Neuroblastoma

- Most common extracranial tumor during childhood; poor outcomes for metastatic disease<sup>1,2</sup>
- Orphan Disease opportunity: ~650 cases per year in the U.S.<sup>3</sup>

1. Taurolidine specifically inhibits growth of neuroblastoma cell lines in vitro <http://www.ncbi.nlm.nih.gov/pubmed/24762556>

2. Taurolidine cooperates with antineoplastic drugs in neuroblastoma cells. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4279442/>

3. Pediatric Neuroblastoma – eMedicine. <http://emedicine.medscape.com/article/988284-overview>

# CorMedix Summary and Value Proposition

- U.S. FDA Fast-track status with Phase 3 hemodialysis trial underway
  - Proven clinical utility in EU post-market observational study
- Granted QIDP Designation – up to 10.5 years potential market exclusivity in U.S.
- Additional pivotal and post-market studies planned to expand Neutrolin use
- Substantial additional value may be unlocked through partnership
  - taurolidine use in medical device applications and oncology
  - Two research collaborations in place and multiple discussions ongoing
- Neutrolin<sup>®</sup> currently available in EU and Middle East (CE Marked)



NYSE MKT: **CRMD**



1430 Route 206  
Suite 200  
Bedminster, NJ 07921



@CorMedixInc



908.517.9500 (ph)



**Investor & Media Contact**

Tiberend Strategic Advisors, Inc.  
Josh Drumm, Ph.D.

[jdrumm@tiberend.com](mailto:jdrumm@tiberend.com); 212-375-2664

Janine McCargo

[jmccargo@tiberend.com](mailto:jmccargo@tiberend.com); 646-604-5150