



Harnessing Taurolidine Technology

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

Oppenheimer 29th Annual Healthcare Conference
March 19, 2019

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 Phase 3 development program for Neutrolin in the U.S.; our need for and 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 American; 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.

FINANCIAL SUMMARY

Founded	January 2006
Exchange: Ticker	NYSE American: CRMD
Headquarters	Berkeley Heights, NJ
Employees (U.S.)	22
Common Stock O/S	119.0 Million
Pref/CS Equivalents	17.8 Million
Warrants Outstanding	16.0 Million
Cash at December 31, 2018	\$17.6 Million
Convertible Debt	\$6.1Million
Recent Share Price	\$1.85
Recent Market Cap	\$220 million





MISSION **STATEMENT**

To harness our taurolidine technology for the prevention and treatment of infectious, inflammatory, and other serious diseases

First commercial product candidate: Neutrolin®

A novel, non-antibiotic antimicrobial solution designed to prevent costly and dangerous bloodstream infections associated with the use of central venous catheters

CORPORATE HIGHLIGHTS

NEUTROLIN

Non-antibiotic antimicrobial solution designed to prevent costly and dangerous bloodstream infections associated with the use of central venous catheters.

Awarded FDA Fast Track status, exclusivity as a New Chemical Entity and designated as a Qualified Infectious Disease Product.

10 years of market exclusivity with additional 6 months exclusivity if approved for pediatric use.

SIGNIFICANT MARKET OPPORTUNITY

Current estimates of annual need for catheter lock solutions in the U.S. for hemodialysis alone are 30 to 40 million vials. Meeting the needs in other indications requires up to several hundred million more vials per year.

Approved in Europe via CE Mark for use in multiple indications requiring use of central venous catheters.

PHASE 3 STOPPED FOR EFFICACY

LOCK-IT-100 was a multicenter, randomized, double-blind, active control trial that demonstrated efficacy / safety of Neutrolin in preventing CRBSIs, for those receiving hemodialysis for end stage renal disease.

Study was terminated in August 2018. DSMB had recommended to stop the study for efficacy with no safety concerns, at the Interim Review. Recently unblinded data revealed a 71% reduction in risk of occurrence of CRBSIs, with a p-value of 0.0006.

FDA meeting 1Q 2019 to determine regulatory pathway: Discussions ongoing.

TAUROLIDINE TECHNOLOGY PLATFORM

Developing a pipeline of antimicrobial medical devices, with active programs in surgical sutures and meshes, and topical hydrogels.

Developing pipeline for oncology as taurolidine may enhance activity of oncologic agents.

NEUTROLIN®

Non-antibiotic Anti-infective To Prevent CRBSI

NEUTROLIN®

Proprietary Formulation

- ✓ **Taurolidine – 1.35%** (anti-infective, anti-inflammatory)
- ✓ **Heparin – 1000 I.U./ml** (anti-coagulant; current standard of care)
- ✓ **Citrate – 3.5%** (pH buffer)



Neutrolin is an investigational drug not approved in the US

KEY BENEFITS OF NEUTROLIN®

Prevents and reduces bloodstream infection. Bacteria and fungi, Antibiotic-resistant strains, No reported resistance in a clinical setting

Neutrolin® is used to fill catheter lumens when they are not in use, keeping them sterile and preventing microbial colonization and biofilm formation

Inhibits peptide crosslinking in microbial cell walls

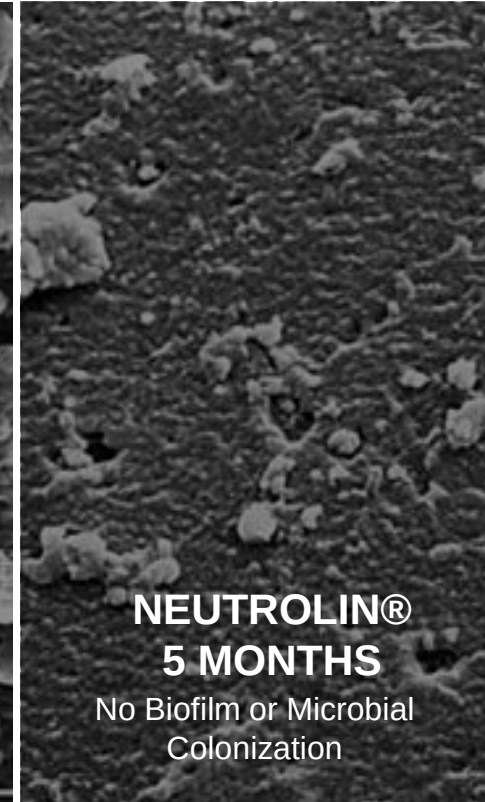
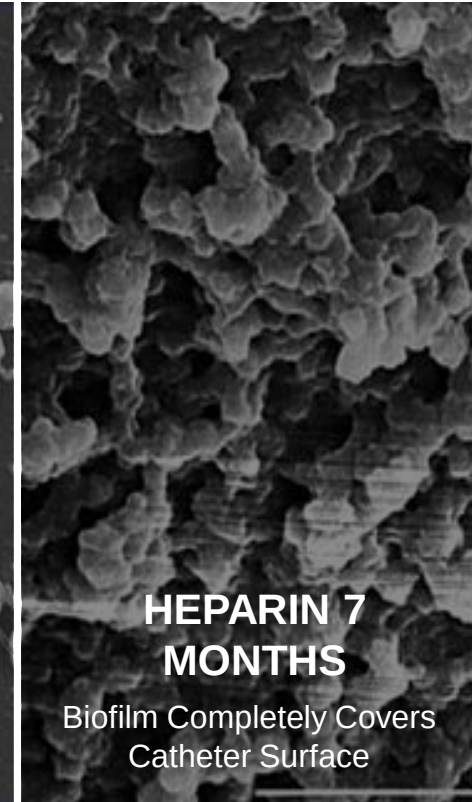
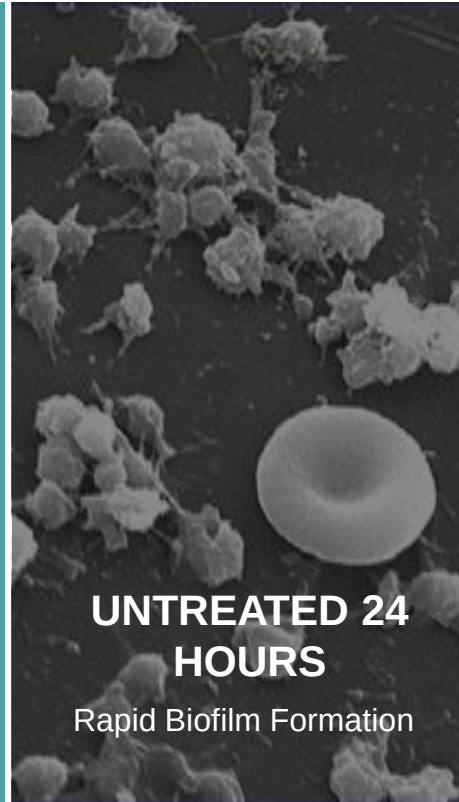
Neutralizes endotoxins, exotoxins, and lipopolysaccharides released by bacteria

MEDICAL OPPORTUNITY

Despite improvements and initiatives to control infection, biofilm develops very quickly and can lead to life-threatening complications, costing the U.S. healthcare system billions of dollars annually

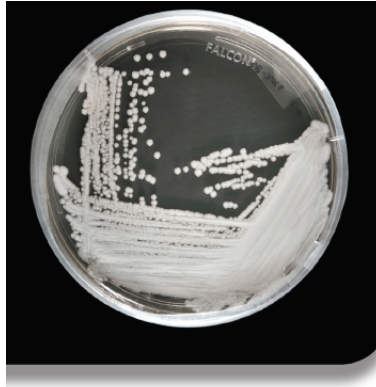
SIGNIFICANT UNMET NEED

- 01** 250,000 catheter-related bloodstream infections (CRBSIs) per year in the U.S.
- 02** Bacteria are significantly more resistant to antibiotics within a biofilm
- 03** Microbial biofilms responsible for majority of CRBSI
- 04** CRBSI are associated with substantial morbidity, mortality, and excess healthcare costs



A NEW SUPERBUG

Hard to Detect But Easy to Cause Bloodstream Infections



Candida auris: A drug-resistant germ that spreads in healthcare facilities

Candida auris (also called *C. auris*) is a fungus that causes serious infections. Patients with *C. auris* infection, their family members and other close contacts, public health officials, laboratory staff, and healthcare workers can all help stop it from spreading.

Why is *Candida auris* a problem?



It causes serious infections. *C. auris* can cause bloodstream infections and even death, particularly in hospital and nursing home patients with serious medical problems. More than 1 in 3 patients with invasive *C. auris* infection (for example, an infection that affects the blood, heart, or brain) die.



It's often resistant to medicines. Antifungal medicines commonly used to treat *Candida* infections often don't work for *Candida auris*. Some *C. auris* infections have been resistant to all three types of antifungal medicines.



It's becoming more common. Although *C. auris* was just discovered in 2009, it has spread quickly and caused infections in more than a dozen countries.



It's difficult to identify. *C. auris* can be misidentified as other types of fungi unless specialized laboratory technology is used. This misidentification might lead to a patient getting the wrong treatment.



It can spread in hospitals and nursing homes. *C. auris* has caused outbreaks in healthcare facilities and can spread through contact with affected patients and contaminated surfaces or equipment. Good hand hygiene and cleaning in healthcare facilities is important because *C. auris* can live on surfaces for several weeks.

CDC GUIDELINES UPGRADED IN 2011 **TO RECOMMEND USE OF ANTIMICROBIAL LOCKS**

CDC Recommendation

Use prophylactic antimicrobial lock solution in patients with long-term catheters who have a history of multiple CRBSI despite optimal maximal adherence to aseptic technique.

Although antimicrobial locks are associated with a significant reduction in CRBSI, their use was limited because of:

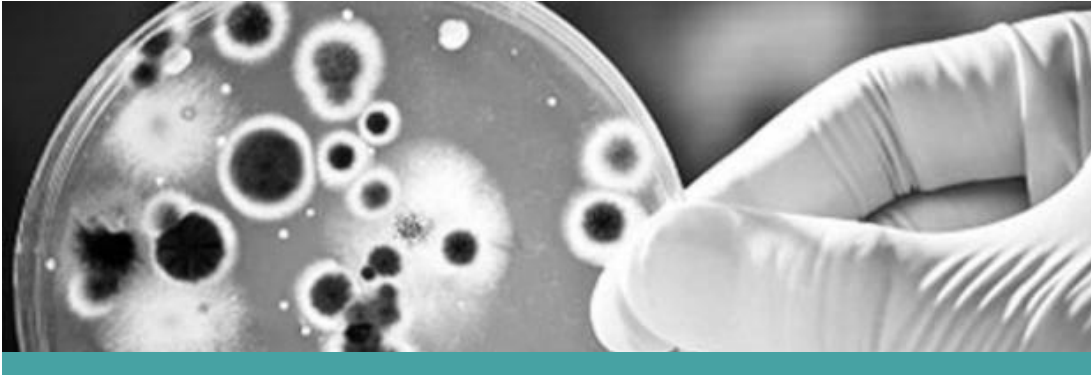
- Potential for side effects
- Toxicity
- Emergence of resistant organisms
- Allergic reactions



Bottom Line: There is a recognized need for antimicrobial lock solutions, but antibiotic lock solutions have trade-offs that limit their recommended applications. There is a need for an antimicrobial lock solution without negative trade-offs.

NEUTROLIN®

Non-antibiotic Anti-infective To Prevent CRBSI

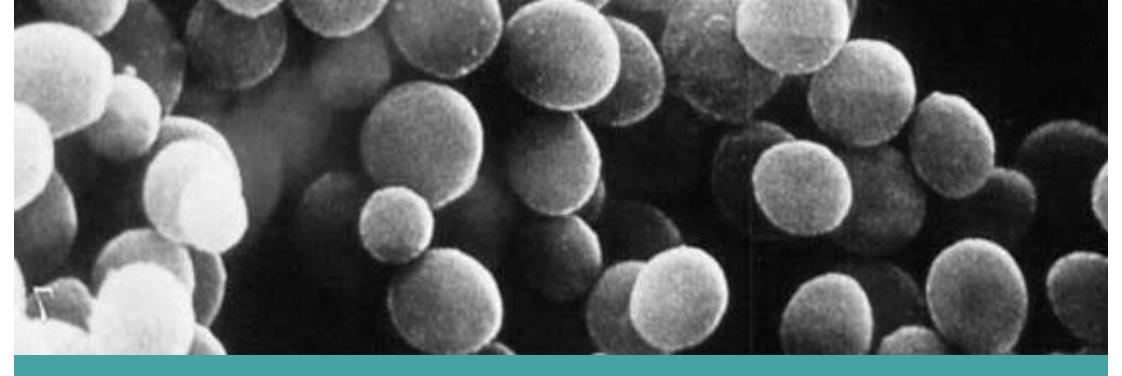


NO MICROBIAL RESISTANCE SHOWN

Adaptation of microorganisms to taurolidine has not yet emerged as a factor in the pathogenesis of CRBSI

Bacterial resistance has not been reported, as taurolidine's mode of action **resembles an anti-infective rather than an antibiotic**

Broadly active against bacteria, including **antibiotic-resistant** MRSA, VISA, VRSA, ORSA and VRE



BROAD SPECTRUM OF COVERAGE

Gram Positive Microorganisms

Coagulase-negative *Staphylococcus* species and *Staphylococcus aureus*

Gram Negative Microorganisms

Klebsiella pneumoniae, *Escherichia coli* and *Pseudomonas aeruginosa*

Clinically Relevant Fungi

Aspergillus fumigatus, *Candida albicans* and *Candida auris*

Europe: NEUTROLIN CLINICALLY **VALIDATED IN REAL WORLD STUDY**

Neutrolin Usage Monitoring Program (NUMP)

Open-label, post-market observational study

PRIMARY GOAL

Monitor safety and efficacy of CE Marked Neutrolin in preventing infection and thrombosis

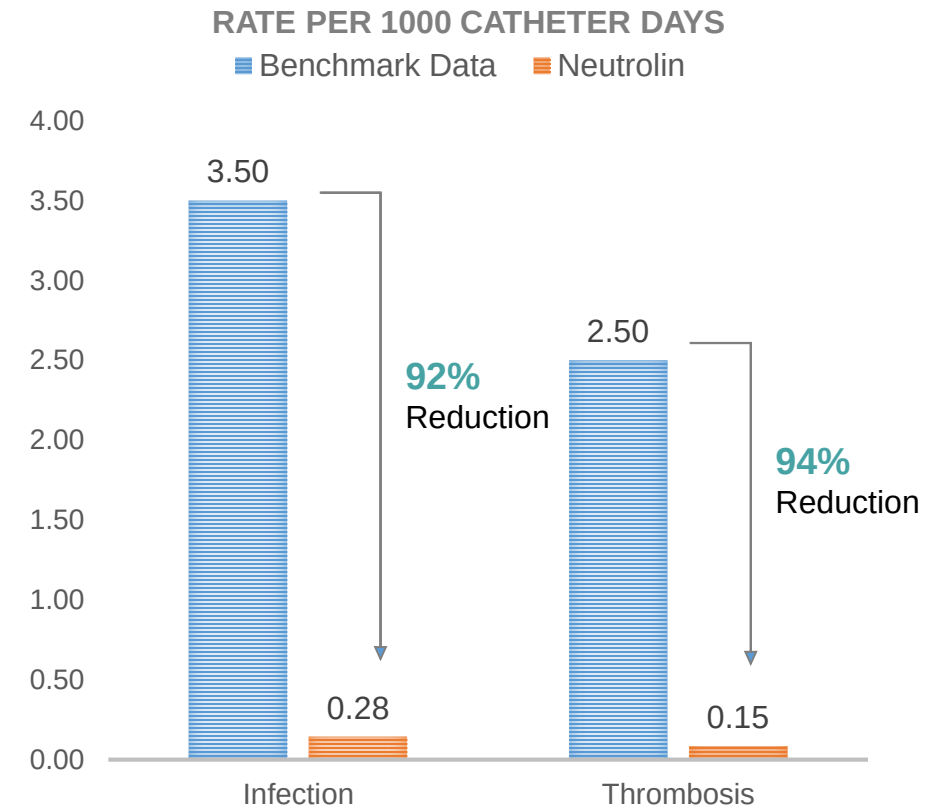
Positive results consistent with prior clinical studies:

- **20** centers
- **201** hemodialysis patients
- **47,118** catheter days

Data accumulated from **NUMP** registry add support to NDA

Final results published in the *European Journal of Clinical Microbiology and Infectious Diseases*: **Reidenberg, BE, Wanner, C., Polsky, B et al. Eur J Clin Microbiol Infect Dis (Dec 06, 2017)**

Neutrolin Significantly Reduced Infection and Thrombosis



¹CDC Guidelines for the Prevention of Intravascular Catheter Related Infections; O'Grady et al., 2011;

²Morris P, Knechtle SJ. Kidney Transplantation - Principles and Practice. Saunders, 2013. Print.;

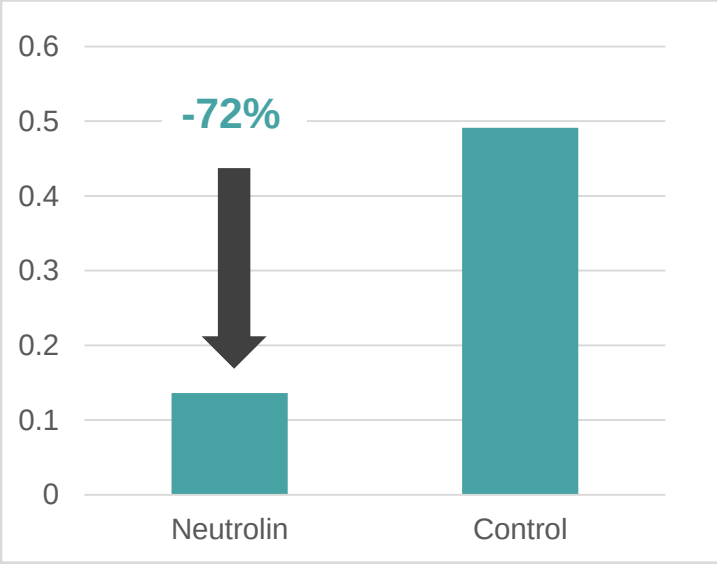
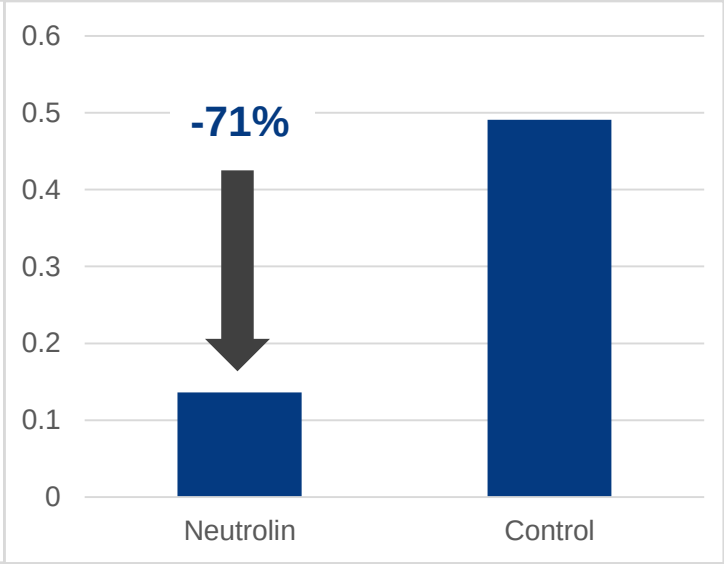
³Napalkov P, Felici DM, Chu LK, Jacobs JR, Begelman SM. Incidence of catheter-related complications in patients with central venous or hemodialysis catheters: a health care claims database analysis.

LOCK-IT 100 PREVENTING CRBSI IN DIALYSIS PATIENTS



DESIGN	OBJECTIVE	PRIMARY ENDPOINT	SECONDARY ENDPOINTS
Phase 3, multicenter, double-blind, randomized (1:1), active control (heparin) Event-driven: 56 CRBSI events required to complete the study; 28 CRBSI events at Interim Analysis met pre-specified efficacy endpoint; trial stopped for efficacy	Demonstrate the efficacy and safety of Neutrolin® as a catheter lock solution for the prevention of CRBSI and the incidence of treatment-emergent adverse events compared to heparin (1000 u/ml) Goal to achieve significant reduction in infection rate vs. heparin was accomplished	Time to occurrence of CRBSI Treatment effect is a minimum of 55% vs. the control arm Recently unblinded data, at the final total of 41 events, revealed a 71% reduction in risk of occurrence of CRBSIs, with a p-value of 0.0006	Catheter patency Catheter removal There were no statistically significant differences between the Neutrolin arm and the control arm for both secondary endpoints

TOPLINE RESULTS OF LOCK-IT 100 STUDY

	Interim Analysis	Full Study
Total CRBSIs	28	41
Total Subjects	653	795
Neutrolin Reduced CRBSIs by:	72%	71%
Neutrolin (control) Event Rates*	0.136 (0.491)	0.133 (0.465)
p-value	0.0034	0.0006
		

*Event Rate is per 1,000 Catheter-Days

SECONDARY ENDPOINTS: NO STATISTICALLY SIGNIFICANT DIFFERENCES BETWEEN NEUTROLIN & CONTROL ARMS

Catheter Removal: $p=0.42$

	Neutrolin	Control Arm
Event Rate*	3.48	3.23
Subjects	236 out of 397	224 out of 398

Loss of Catheter Patency: $p=0.10$

	Neutrolin	Control Arm
Event Rate*	1.01	0.74
Subjects	64 out of 397	48 out of 398

FDA MEETING **ON LOCK-IT-100**

- Productive meeting
- Agreed CRMD can request LPAD Pathway
- FDA reviewed preliminary analyses of database up to Interim Analysis (654 subjects)
- FDA requested analyses of full dataset (795 subjects) whose topline results disclosed Jan. 2019
- Detailed analyses of full dataset to be completed over the next several weeks
- CRMD will continue agency discussions on single-study NDA submission
- If positive FDA feedback, could be approved for marketing in 2020

FDA RECOGNIZES **POTENTIAL OF NEUTROLIN**

10.5 YEARS

Potential Market Exclusivity

APPROVAL PATHWAY

Designated an investigational new drug by FDA

- Granted New Chemical Entity (NCE) Status
5 years exclusivity
- Granted Qualified Infectious Disease Product (QIDP) **5 years exclusivity**
- Approval for pediatric use provides additional
6 Months exclusivity

CORMEDIX MANAGEMENT TEAM

Khoso Baluch	CEO	  
Robert Cook	CFO	     
Paul Chew, MD	Chief Medical Officer	  
Jack Armstrong	EVP Technical Operations	    
Elizabeth Masson	EVP & Head Of Clinical Operations	  
Antony Pfaffe, MD	Chief Scientific Officer	  
John Ortiz	VP Regulatory Affairs & Quality Assurance	  

CURRENT CORMEDIX PIPELINE

DRUG PIPELINE

Product Category	Indication	Preclinical	Phase 1	Phase 2	Phase 3	Marketed
Neutrolin® U.S.	Hemodialysis	Stopped for Efficacy at Interim Review: FDA Discussions Ongoing				
	Oncology					
	ICU / CCU					
CMDX-001	Pediatric Neuroblastoma*					

* Orphan Disease Opportunity

MEDICAL DEVICE PIPELINE

Product Category	Indication (s)	Discovery	In Vitro PoC	In Vivo PoC	PMA	Marketed
Neutrolin® Europe	Catheter lock solution	CE Marked				
CMDX-006: Synthetic sutures	Wound closure/surgery					
CMDX-008: Surgical meshes	Burns and hernia					
CMDX-007: Topical hydrogels	Common burns/foot ulcers					
Nanoparticle Hydrogel**	Severe burn injury					

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THANK YOU

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