

Harnessing **Taurolidine** Technology

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

**21st Annual H.C. Wainwright Global Investment
Conference**
September 9, 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.)	23
Common Stock O/S	23.8 Million
Pref/CS Equivalents	6.1 Million
Warrants Outstanding	2.3 Million
Cash at June 30, 2019	\$26.4 Million
Recent Share Price	\$7.93
Recent Market Cap	\$189 million





MISSION **STATEMENT**

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

First commercial product candidate in the US: 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.

PHASE 3 COMPLETED

LOCK-IT-100 was a multicenter, randomized, double-blind, active control trial that demonstrated efficacy / safety of Neutrolin in preventing catheter-related bloodstream infections (CRBSIs), for those receiving hemodialysis through a central venous catheter for end stage renal disease ESRD).

The study was terminated in August 2018 after the DSMB had recommended to stop the study for efficacy with no safety concerns, at the prespecified Interim Analysis. For the full study population the data revealed a 71% reduction in risk of occurrence of CRBSIs, with a p-value of 0.0006.

Pre-NDA meeting expected during 4th quarter 2019; approval anticipated 2nd half of 2020.

SIGNIFICANT MARKET OPPORTUNITY

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

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

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.

* Company estimate based on independent research

COMMERCIAL OPPORTUNITY

Neutrolin's U.S. commercial opportunity as a catheter lock solution for hemodialysis and additional indications

SIGNIFICANT UNMET NEED

- **Over 180 extensive interviews with nephrologists, oncologists, TPN healthcare providers** have reconfirmed significant unmet need with catheter-related blood stream infections.
- Research suggests practitioners agree that a catheter-related infection is the most clinically concerning complication associated with central line use.
- Undisclosed market research firm claims **the receptibility to Neutrolin was among top 10% of 100 new products tested.***

MARKET SIZE

- Hemodialysis segment was estimated to require around **40 million** catheter** lock solutions per year and growing.
- Oncology and TPN segments were estimated to be almost **150 million** catheter** lock solutions per year and growing.
- Market opportunity also exists for use in ICU setting. Research is ongoing to better define the market opportunity.

MANUFACTURING & SUPPLY

- Successfully concluded technical transfer and validation of manufacturing process, which has enabled production at 3 different manufacturing locations.
- Longer term, manufacturing expected at 2 or more manufacturing sites.
- Upon FDA approval, anticipated in the 2nd half of 2020, will be available in the U.S. with initial product manufactured in Europe.

REIMBURSEMENT

- Falls within the criteria as a new chemical entity (NCE) and should therefore be eligible for TDAPA.***
- Neutrolin should be eligible for reimbursement outside of the ESRD bundle for at least the first two years.
- TDAPA applies for hemodialysis patients only. Reimbursement in the outpatient oncology and TPN areas is generally done on a fee per service basis and is highly leveraged for value due to the increased incidence of CRBSIs.

* Across many disease states and treatment modalities, including very-innovative products such as cell therapy

** Company estimates based on independent research

***Transitional Drug Add-on Payment Adjustment for end stage renal disease

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

FDA RECOGNIZES **POTENTIAL OF NEUTROLIN**

10.5 YEARS

Potential Market Exclusivity

APPROVAL PATHWAY

Designated an investigational new drug by FDA

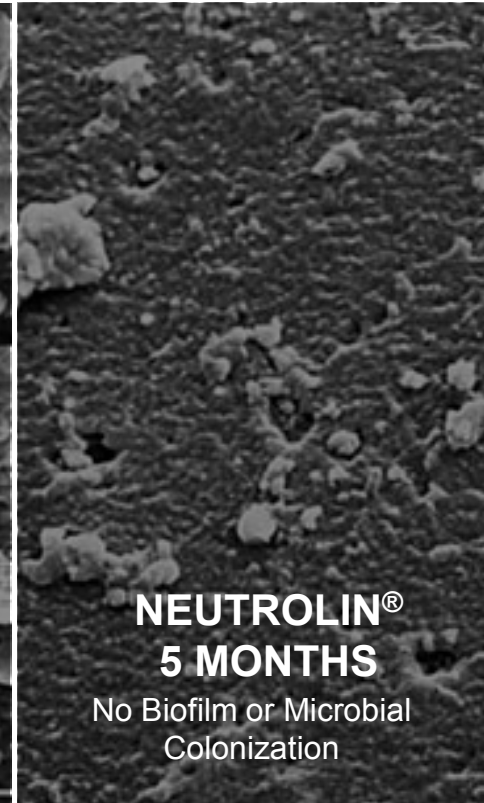
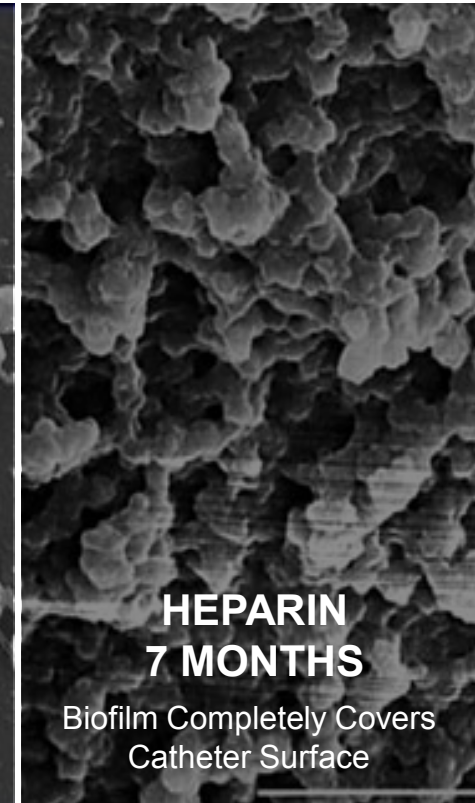
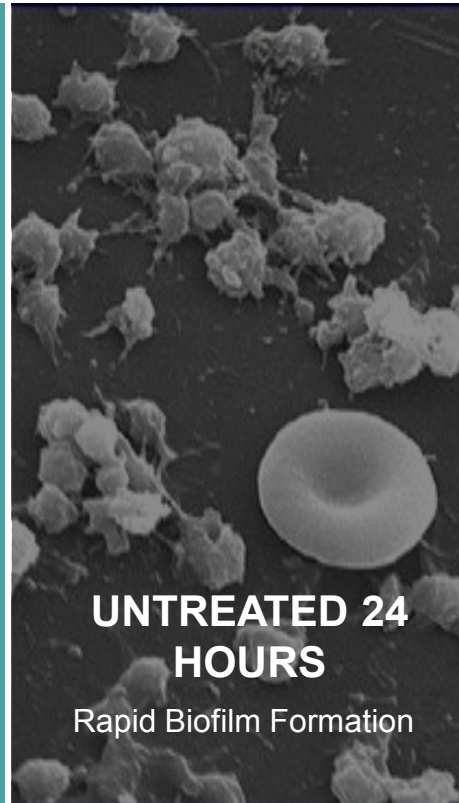
- Granted New Chemical Entity (NCE) Status
5 years exclusivity
- Granted Qualified Infectious Disease Product (QIDP) **5 years exclusivity**
- Approval for pediatric use would provide additional
6 Months exclusivity

MEDICAL OPPORTUNITY

Despite improvements and initiatives to control infection, catheter biofilm develops within 24 hours and can lead to life-threatening infections, costing the U.S. healthcare system billions of dollars annually

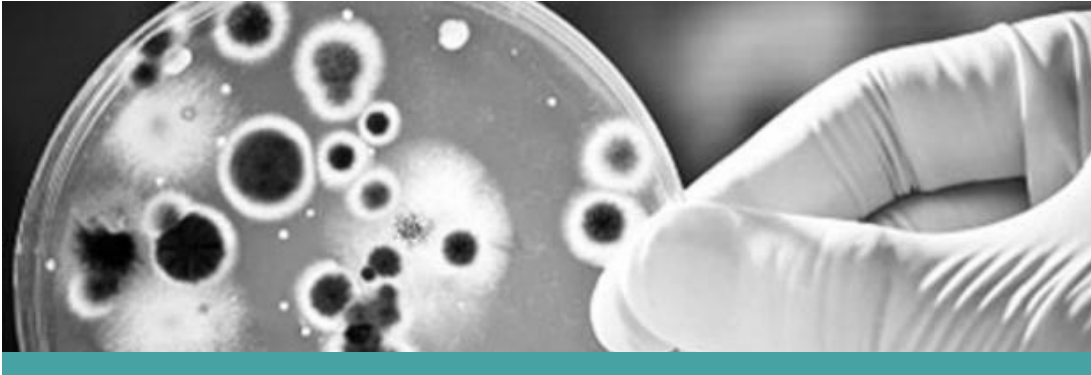
SIGNIFICANT UNMET NEED

- 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** Antibiotic resistant pathogens associated with CRBSIs
- 04** CRBSI are associated with substantial morbidity, mortality, and excess healthcare costs



NEUTROLIN®

Non-antibiotic Anti-infective To Prevent CRBSI

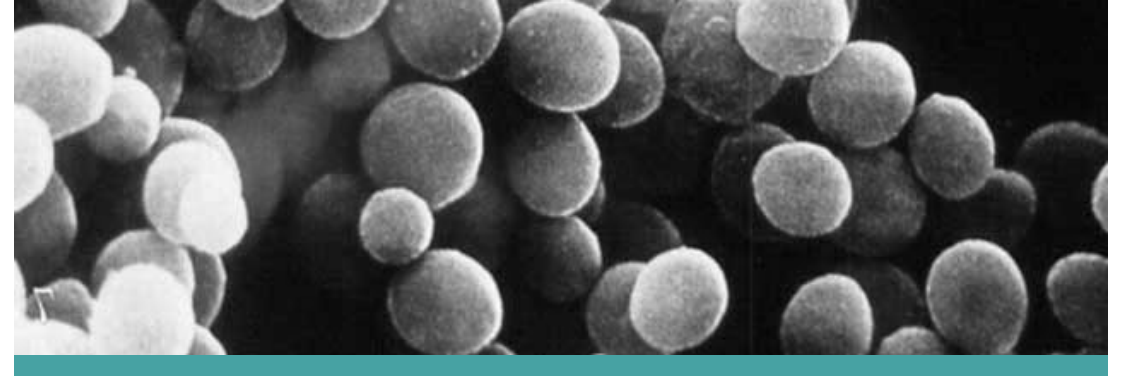


NO MICROBIAL RESISTANCE SHOWN

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 TAUROLIDINE 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*

LOCK-IT 100 PREVENTING CRBSI IN DIALYSIS PATIENTS



DESIGN

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

OBJECTIVE

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

PRIMARY ENDPOINT

Time to occurrence of CRBSI

Treatment effect is a minimum of 55% vs. the control arm

Final study data of 41 events revealed a 71% reduction in risk of occurrence of CRBSIs, with a p-value of 0.0006

SECONDARY ENDPOINTS

Catheter patency

Catheter removal

There were no statistically significant differences between the Neutrolin arm and the control arm for both secondary endpoints

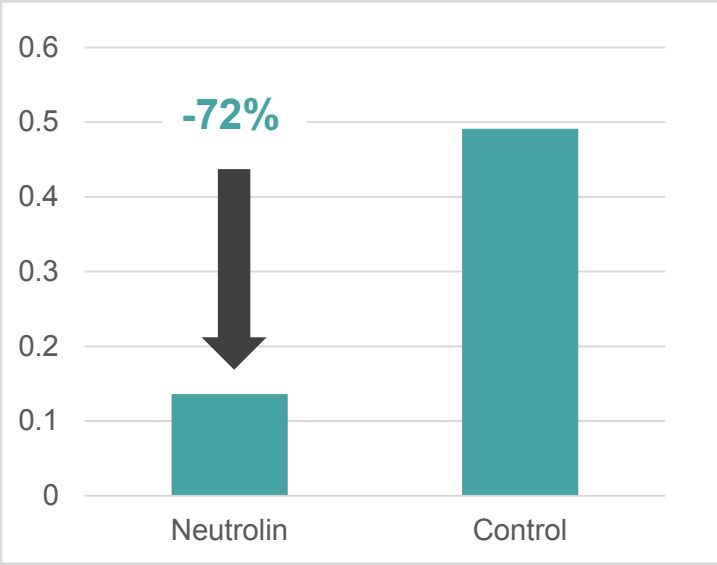
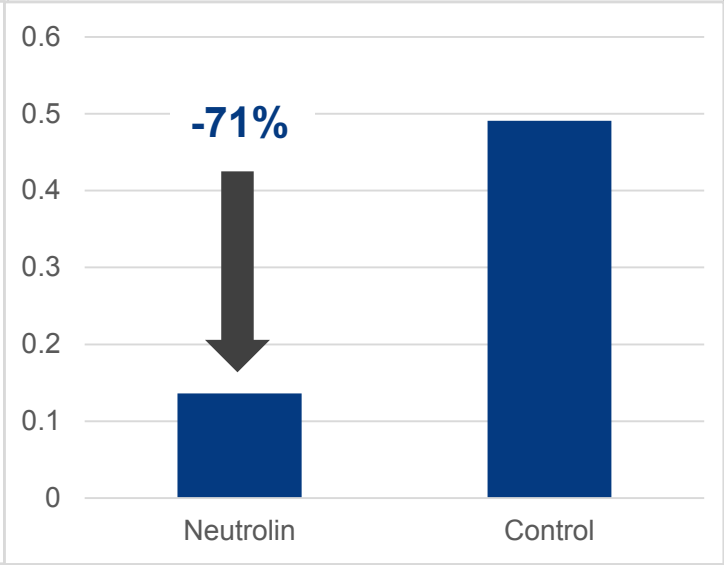
LOCK-IT 100 **BASELINE DEMOGRAPHICS (I)**

Demographic	Neutrolin (403) %	Heparin (403) %
Mean age (years) (SD)	60.8 (14.22)	60.9 (14.39)
<65 years (%)	59.3	58.6
≥ 65 to < 75 years (%)	24.6	23.6
≥ 75 years (%)	16.1	17.9
Female (%)	45.7	38.2
White (%)	61.5	65.0
Black or African-American (%)	31.3	27.8
Asian (%)	3.7	4.5
Other Race (%)	3.4	2.7
Hispanic or Latino Ethnicity (%)	43.9	46.9

LOCK-IT 100 **BASELINE DEMOGRAPHICS (II)**

Demographic	Neutrolin (403) %	Heparin (403) %
Diabetes (%)	69.0	68.7
BMI (mean) kg/m ²	29.7	29.2
Months Since 1 st Dialysis (SD)	21.2 (37.5)	19.8 (37.0)
≤ 12 Months on Dialysis (%)	67.5	68.5
Internal Jugular CVC (%)	92.1	90.6
Subclavian CVC (%)	7.4	7.7
Other CVC (%)	0.5	1.5

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: $p=0.416$

	Neutrolin (n=397)	Control Arm (n=398)
Event Rate*	3.48	3.23
Subjects	236 out of 397	225 out of 398

Loss of Catheter Patency: $p=0.12$

	Neutrolin	Control Arm
Event Rate*	0.99	0.74
Subjects	63 out of 397	48 out of 398

LOCK-IT 100 **SECONDARY ENDPOINT**

Catheter Removal for Positive Reasons Full Population Analysis at 41 CRBSIs Post-Hoc

	Neutrolin (N=397)	Heparin (N=398)
No Longer Needed for HD	162	131
Improved Renal Function	0	1
Total Removals-Positive Reasons	162 (41)	132 (33)
Total Catheter-Days Follow-up	67,780	69,465
Positive Events/1000 CD (95% CI)	2.39 (2.05, 2.79)	1.90 (1.60, 2.25)

CD= Catheter-Days

LOCK-IT 100 **SECONDARY ENDPOINT**

Catheter Removal for Negative Reasons Full Population Analysis at 41 CRBSIs Post-Hoc

	Neutrolin (N=397)	Heparin (N=398)
CRBSI (%)	8 (2.0)	29 (7.3)
All Cath. Malfunction-Dysfunction (%)	62 (16)	57 (14)
Other (%)	4 (1.0)	7 (1.8)
Total	74 (19)	93 (23)
Total Catheter-Days Follow-up	67,708	69,318

CD= Catheter-Days

LOCK-IT 100 **SECONDARY ENDPOINT**

Loss of Catheter Patency Full Population Analysis at 41 CRBSIs Post-Hoc

	Neutrolin (N=397) (%)	Heparin (N=398) (%)
Loss of Catheter Patency (%)	63 (16)	48 (12)
rt-PA for Loss of Patency (%)	46 (12)	33 (8.3)
CR for Loss of Patency (%)	17 (4.3)	15 (3.8)
Total Catheter Days Follow-up	63,582	65,260
Rate/1000 Catheter Days (95% CI)	0.99 (0.77, 1.27)	0.74 (0.55, 0.98)
p-value**	.12	

* CR = Catheter Removal for Loss of Patency Malfunction/Dysfunction

** Log-Rank Test

LOCK-IT 100 SAFETY

Treatment Emergent Serious Adverse Events Incidence $\geq 2\%$ in Either Treatment Arm (Safety Population)

Deaths & AE Preferred Terms	Neutrolin (N=398) %	Heparin (N=399) %
Deaths	4.5	5.3
Device-related Infection	1.5	2.0
Pneumonia	3.0	5.3
Sepsis	2.3	3.5
Acute Myocardial Infarction	1.3	3.3
Cardiac Failure, Congestive	3.0	1.8
Fluid Overload	3.5	3.0
Hypertension	1.0	2.5
Hyperkalemia	2.5	2.0
Respiratory Failure	1.8	2.3

CONCLUSION

01

LOCK-IT-100, a landmark study, showed that in ESRD subjects with hemodialysis via a central venous catheter, Neutrolin® catheter lock solution significantly reduced catheter-related bloodstream infections, a leading cause of mortality in HD

02

Compared to heparin, there was no significant difference in either catheter removals for any reason or loss of catheter patency

03

Treatment-emergent serious adverse events were infrequent and similar between Neutrolin and heparin arms

CORMEDIX MANAGEMENT TEAM

Khoso Baluch	Chief Executive Officer	  
Robert Cook	Chief Financial Officer	    
Phoebe Mounts, PhD, JD	EVP and General Counsel	   
Paul Chew, MD	Chief Medical Officer	  
Jack Armstrong	EVP Technical Operations	    
Elizabeth Masson	EVP & Head Of Clinical Operations	  

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 Drug Designation

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

NYSE American: CRMD

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