Corporate Presentation

June 2023



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Who is CorMedix?

- CorMedix is a publicly listed (Nasdaq: CRMD), small cap pre-commercial stage biopharma company developing therapeutic products for the prevention and treatment of life-threatening conditions and diseases
- Our lead asset is DefenCath, a novel, first-in-class, non-antibiotic antimicrobial catheter lock solution designed to reduce catheter related bloodstream infections (CRBSIs) and maintain catheter patency in patients with central venous catheters (CVCs)
- Initial target indication for DefenCath is the reduction of CRBSIs in hemodialysis patients receiving chronic hemodialysis through a CVC, a critical unmet medical need with a high rate of incidence, and high rates of morbidity and mortality for the hemodialysis patient population
- CorMedix resubmitted the DefenCath NDA in May 2023, FDA has accepted the NDA for filing as a Class 2 resubmission with a 6-month review, and has granted a PDUFA target action date of November 15, 2023
- DefenCath is expected to serve a sizable commercial market opportunity spanning both the hospital inpatient as well as outpatient dialysis segments, with inpatient reimbursement already established upon FDA approval via NTAP
- DefenCath has the potential to receive 10 ½ years of market exclusivity pursuant to FDA approval of the NDA as a New Chemical Entity (NCE, 5 years) and Qualified Infectious Disease Product (QIDP, 5 years) with an additional 6 months upon completion of a pediatric hemodialysis study, as well as IP protection covering the product through 2042

CorMedix Executive Leadership Team

Joe Todisco Chief Executive Officer	2022	 Chief Commercial Officer of Amneal Specialty Co-founder and Chief Executive of Gemini Laboratories Commercial Strategy and business development at Ranbaxy 	RANBAXY
Matt David, MD EVP, Chief Financial Officer	2020	 Head of Strategy at Ovid Therapeutics Life science focused investment banker at BofA, Thomas Weisel Partners and Piper Jaffray Former Pharma research analyst at Lehman Brothers 	FREQUENCY THERAPEUTICS Bankof America Merrill Lynch LEHMAN BROTHERS
Phoebe Mounts, PhD, JD EVP, General Counsel, Legal, Regulatory, Compliance	2019	 Partner at Morgan Lewis, specializing in FDA law Faculty at Johns Hopkins School of Public Health Ph.D. in molecular biology 	Morgan, Lewis & Bockius LIP COUNTRICATE AT LAW DOINS HOPKINS BIODINERG GEOOR BIODINERG GEOIOR BIODINERG GEOIOR BIODINERG GEOIOR BIODINERG GEOIOR BIODINERG GEOIOR BIODINERG GEOIOR
Liz Masson Hurlburt EVP, Clinical and Medical Affairs	2017 Led LOCK-IT-100 clinical study program	 VP of Clinical Operations at Gemphire Therapeutics Additional renal area experience from Rockwell Medical 	Gemphire Qaccelovance Therapoules Qaccelerate Advance Achieve ORCCKWELL MEDICAL
Erin Mistry EVP, Chief Commercial Officer	2020	 VP of Value Access at Intarcia Therapeutics Senior Managing Director Syneos Health – global P&L of Value & Access Practice with 12 years consulting 	Interspeutics.Inc. AstraZenecca Mealth MedImmune DukeHealth
	 Joe Todisco Chief Executive Officer Matt David, MD EVP, Chief Financial Officer Phoebe Mounts, PhD, JD EVP, General Counsel, Legal, Regulatory, Compliance Liz Masson Hurlburt EVP, Clinical and Medical Affairs Erin Mistry EVP, Chief Commercial Officer 	Joe Todisco Chief Executive Officer2022Matt David, MD EVP, Chief Financial Officer2020Phoebe Mounts, PhD, JD EVP, General Counsel, Legal, Regulatory, Compliance2019Liz Masson Hurlburt EVP, Clinical and Medical Affairs2017 Led LOCK-IT-100 clinical study programErin Mistry EVP, Chief Commercial Officer2020	 Chief Commercial Officer of Amneal Specialty Co-founder and Chief Executive of Gemini Laboratories Commercial Strategy and business development at Ranbaxy Matt David, MD EVP, Chief Financial Officer 2020 Head of Strategy at Ovid Therapeutics Life science focused investment banker at BofA, Thomas Weisel Partners and Piper Jaffray Former Pharma research analyst at Lehman Brothers Phoebe Mounts, PhD, JD EVP, General Counsel, Legal, Regulatory, Compliance 2019 Partner at Morgan Lewis, specializing in FDA law Faculty at Johns Hopkins School of Public Health Ph.D. in molecular biology VP of Clinical Operations at Gemphire Therapeutics Additional renal area experience from Rockwell Medical VP of Value Access at Intarcia Therapeutics Senior Managing Director Syneos Health – global P&L of Value & Access Practice with 12 years consulting

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The Problem: CRBSI

Catheter Related Bloodstream Infections



Catheter Related Bloodstream Infections (CRBSI) are a Common and Life-threatening Complication of CVC use

Disease Burden

~80% of patients starting HD (hemodialysis) will have a CVC inserted for vascular access ¹

CRBSIs can occur in 25%-33%⁶ of CVC HD patients, and are caused by a wide range of pathogens-many of which are drug resistant ¹¹

Over 50% of CRBSIs occur within the first 3 months following CVC insertion ¹²

The average time on a CVC is 220 days ²

Health Economics

HD patients with CRBSIs have almost 2x more hospitalizations per year ⁴

Length of hospital stays for HD CRBSI patients are 4x longer and cost 2x more than non-CRBSI patients ^{4,5}

Patients with CRBSI are 3x more likely to die within 90 days¹²

All-payer annual incremental costs of CRBSI is \$2.3B⁶

CRBSI and related healthcare costs arise quickly

Key Takeaways from Inpatient HECON Analysis

9% to 13%

Observed incidence of CRBSI for <u>inpatients</u> with the diagnosis of AKI, CKD or ESRD

92% to 99%

All-cause readmission rate among CRBSI patients, ~80% within 30-days 60% to 72%

30-day readmission rate for **CRBSI recurrence** among CRBSI patients 3x to 5x

Greater 30-day readmission rates for **CRBSI vs noninfected patients** for AKI and CKD patients receiving inpatient hemodialysis

The data showed not only a high rate of CRBSI incidence, but significant readmissions at both <u>30-day</u> and <u>90-day</u> intervals for recurring CRBSIs.

CorMedix performed a retrospective database analysis of the largest hospital discharge database in the US, to assess the proportion of 381,336 HD-CVC patients between 2017-2021 with a diagnosis of AKI, CKD or ESRD among hospitalized inpatients, and to examine the incidence of CRBSIs among the respective hospitalized patient populations and 30-day and 90-day readmissions (for all-cause and for recurring CRBSIs).



CRBSIs Can Increase Hospitalizations, Length of Stay and Negatively Impact Concomitant Conditions

Increases in Hospitalizations and LOS with CRBSIs

	CRBSI	Non CRBSI	P-value
Mean Number of Hospitalizations*	3.79	1.96	<0.05
Hospital Days*	25.0	5.86	<0.05

Increases in Major Complications with CRBSIs

CRBSIs resulted in **higher 1-year incremental rates** of^{3,†}:

Dysrhythmia	26.7%
Congestive Heart Failure	13.4%
Endocarditis	9.4%
Myocardial Infarction	9.2%
Stroke	6.6%

*Both outcomes were significantly higher for CRBSI vs. non-CRBSI hospitalized patients (p<0.05) at 1-year post-CRBSI.

†HR for CRBSI patients were stroke (1.59, 95% CI 1.50-1.69), MI (2.47, 95% CI 2.30-2.64), CHF (1.89, 95% CI 1.79-2.00), endocarditis (14.46, 95% CI 12.21-17.13), and dysrhythmia (2.41, 95% CI 2.31-2.51). BSI, bloodstream infection; CRBSI, catheter-related bloodstream infection; CVC, central venous catheter; ESRD, end-stage renal disease; HD-CVC, hemodialysis with central venous catheter; HR, hazard ratio.

References: 1. Rajagopalan K, et al. Presented at: the American Society of Nephrology (ASN) Kidney Week 2021; November 4-7, 2021; San Diego, California.

2. Rajagopalan K, et al. Presented at: the Academy of Managed Care Pharmacy (AMCP) Nexus 2021; October 20; Denver, Colorado. 3. Data on file. CorMedix Inc. USRDS-Medicare-CrownWeb Linked Analysis. 2021.

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CRBSIs Significantly Increase the Risk of Death

In an analysis of 55,727 CVC-dependent HD patients, mortality rates at 3 months for HD-CVC patients with CRBSI was 3x higher than those without

Kaplan Meier Survival Estimate, Time to Death



Mortality Rates for CRBSI vs Non-CRBSI Patients

Mortality	CRBSI (%)	Non-CRBSI (%)
90 Days	28.4	8.9
180 Days	37.1	14.9
365 Days	46.5	22.9

BSI, bloodstream infection; CRBSI, catheter-related bloodstream infection; CVC, central venous catheter; ESRD, end-stage renal disease; HD, hemodialysis; HD-CVC, hemodialysis with central venous catheter; HR, hazard ratio.

Reference: Massey K, et al. CRBSI incidence and associated mortality risk: Analysis of merged USRDS-Medicare claims. Presented at: the American Society of Nephrology (ASN) Kidney Week 2021; November 4-7, 2021.

CDC Reported Infection Rates and Health Equity Implications: CMS Proposed Policy Improvements for Infection Prevention

Race, Ethnicity, and Socioeconomic Factors Affect BSI Rates

S. aureus BSI Rates by Race/Ethnicity* Rate per 100,000 patients on dialysis per year



*2017-2020 Emerging Infections Program surveillance data. BSI, bloodstream infection. Reference: Rha B, et al. MMWR Morb Mortal Wkly Rep. 2023;72:153-159. CMS Proposes Policies to Improve Patient Safety and Promote Health Equity

CMS Announced on April 10th a proposed rule for inpatient and long-term care hospitals to advance health equity and support underserved communities

The rule would adopt hospital quality measures to foster safety, equity, and reduce preventable harm in the hospital setting

Infection prevention, especially in the disproportionately Black and Hispanic hemodialysis population, fits squarely within this initiative to both improve patient safety AND address health inequity





Our Proposed Solution: DefenCath™

A novel, first-in-class, antimicrobial catheter lock solution, with broadspectrum antibacterial and antifungal activity, designed to reduce CRBSIs and maintain catheter patency in patients with central venous catheters (CVCs)

Targeting Multiple Potential Large Therapeutics Areas

- DefenCath is a novel, first in class, non-antibiotic catheter lock solution, designed to reduce CRBSIs and maintain catheter patency in patients with CVCs
- Our proprietary NCE Taurolidine demonstrates broad spectrum, antimicrobial activity against gram-negative and gram-positive bacteria, multi-drug resistant bacteria, and clinically relevant fungi
- No pharmacologic agents currently approved in the U.S. for the prevention or reduction of CRBSI in patients with CVCs
- DefenCath has the potential to receive 10.5 years of market exclusivity (NCE, QIDP + pediatric exclusivity) and IP coverage through 2042



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Phase 3 LOCK-IT-100 – Compelling Clinical Profile³

Objective: to demonstrate the efficacy and safety of DefenCath as a catheter lock solution for the prevention of CRBSI and the incidence of treatment-emergent adverse events compared to heparin standard of care

Primary endpoint met (time to occurrence of CRBSI) – highly statistically significant efficacy (p = 0.0006)

Secondary safety endpoints met - no statistically significant differences between DefenCath (D) & Heparin (H) control arm for loss of catheter patency and catheter removal

Study 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 without safety concerns and Data Safety Monitoring Board recommended early termination
- Statistical power based on 55% reduction of risk of CRBSI relative to the control arm
- Study conducted in outpatient clinics in a patient population representative of the current demographic of HD patients in terms of race and ethnicity

	Interim Analysis	Full Study	
Total CRBSIs (D / H)	28 (6 D / 22 H)	41 (9 D / 32 H)	
Total Subjects	653	795	
Reduction in Risk of CRBSIs	72%	71%	
p-value	0.0034	0.0006	
Overall, fewer patients had catheters removed due to CRBSIs with DefenCath compared to control (2% vs. 7.3%; p=0.0008).	0.6 0.5 0.4 0.3 0.2 0.1 0 Defencath Control	0.6 0.5 0.4 0.3 0.2 0.1 0 Defencath Control	

Large Addressable Market Opportunity in Hemodialysis

(Inpatient + Outpatient)



Reimbursement Dynamics

NTAP (New Technology Add-On Payment) is an additional payment for drugs that exceed a DRG payment amount by at least one standard deviation

CMS has issued the Inpatient Prospective Payment System ('IPPS") 2024 proposed rule that includes a revised NTAP of up to \$17,111 per hospital stay for DefenCath, provided final NDA approval occurs before July 1, 2024

TDAPA is an add-on payment to the current bundled rate for certain new ESRD drugs

TDAPA is a 2-year transitional payment after which the cost of therapy is included in the revised bundle payment amount

CorMedix is partnering with key stakeholders to present evidence to CMS that DefenCath is not a renal dialysis service, including FDA label, clinical studies, MOA and FDA designation, and therefore should not be included in the ESRD bundle

Company believes that DefenCath should be separately reimbursed with a unique J Code

Separate reimbursement would yield higher utilization in LDOs with longer-term sustainable value

*Source: Internal Company Market Research

reimbursement vs

TDAPA)

Note: NTAP represents reimbursement to inpatient facilities of 75% of the anticipated WAC price of \$1,170 per 3 mL vial, and an average utilization of 19.5 vials per hospital stay. Each 3 ml vial expected to fill a single lumen lock, therefore 2 vials used per treatment.

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NTAP Designation Provides Additional Reimbursement Possibility at Launch to Hospitals

New Technology Add-on Payment (NTAP) designation enables <u>additional payment to hospitals</u> above the standard Diagnosis-Related Group (DRG) payment amount <u>for Medicare patients</u>



Key Customers Types and Settings of Care

Market channel segmentation and channel specific commercial strategy will be essential to a successful commercialization of DefenCath



Health System Strategic Partnerships

- BMC Partnership is a blueprint for other health systems from which we have a legitimate clinical or business need for data
- Pre-approval disease awareness
- DefenCath education and system implementation
- Demonstration of value across care continuum
- CorMedix brand awareness & value growth
- Regional IDN competition & interest in innovation

Pre-Approval





Commercial Execution & Strategy

CorMedix intends to launch first in the inpatient setting, while working simultaneously to obtain outpatient reimbursement clarity. Modest infrastructure required for both settings of care.

Hospital (Inpatient)

A commercial organization of ~30 can provide adequate coverage for launch

- ~6,100 hospitals in the US, per AHA statistics
- ~1,300 hospitals have more than 200 beds
- 70% of all hospitals are part of a hospital system, many of which centralizes decision and standardize protocols.
- CorMedix is actively reviewing options for a hybrid internal/external outsourced approach to prepare for launch in the Hospital market



Dialysis Facility (Outpatient)

A highly focused internal team of ~12 can provide adequate coverage for launch:

- There are ~7,600 dialysis facilities, ~10,000 nephrologists
- 2,500 to 3,000 dialysis facilities provide ~ 70% of the opportunity
- 5 large dialysis organizations* account for >85% of the dialysis patients; central decision making
- Top 15 states account for ~ 70% of the patients
- CorMedix has been laying the groundwork and building a highly experienced internal team to focus on the outpatient dialysis setting

Hospital size, standardization at system level, along with dialysis facility concentration and corporate owners allows for efficient deployment of resources (sales reps, medical affairs and market access)

* In US, the largest dialysis providers include DaVita, Fresenius, US Renal Care, Dialysis Clinic Inc., and American Renal Associates.

DefenCath Regulatory & Manufacturing Background

- CorMedix announced the completion of the DefenCath submission in July 2020, announced receipt of a complete response letter (CRL) in March of 2021. The NDA was subsequently resubmitted to FDA in February of 2022 and received a second CRL in August of 2022 related to deficiencies in compliance at the primary manufacturing site as well as supplier of heparin API for an unrelated API
- Since August 2022, the Company has worked to improve its supply chain, engaging compliance consultants to provide support to the primary CMO for the implementation of corrective actions, as well as securing an alternate supplier of heparin API, and engaging two back-up CMOs, Alcami and Seigfried Hameln
- The Company completed a Type A meeting in April 2023 with FDA to discuss guidance with respect to the DefenCath NDA resubmission, and following the receipt of FDA Meeting minutes in May 2023, resubmitted the DefenCath NDA. The NDA has been accepted for filing as a class 2 resubmission with a 6-month review, and a PDUFA target action date of November 15, 2023
- The FDA meeting minutes confirm FDAs guidance during the Type A Meeting:
 - FDA informed CorMedix that it is in receipt of the close out report for inspectional observations received from its existing contract manufacturing organization ("CMO 1"), and NDA resubmission with CMO 1 can be done at the Company's discretion. The FDA may conduct a pre-approval inspection at the facility as part of the NDA review process
 - Based on guidance from FDA, CorMedix resubmitted the NDA application with manufacturing data generated at the existing CMO and utilizing both the existing source of heparin API ("API 1") as well as a new supplier of heparin API ("API 2")
 - As part of the validation of API 2, the Company will be adding a 3 mL single-dose vial to its 5 mL commercial presentation to meet market preferences and demand

Financial Highlights

Key Statistics

Balance Sheet

Exchange	NASDAQ Global Market	Cash and short-term investments*	\$55.6 million**
Common Stock	45.4 million shares as of 5/10/2023	Debt	None
Market cap***	~\$250 million		

* Excluding restricted cash ** as of 3/31/2023 *** as of 6/20/2023

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CorMedix's Key Investment Highlights

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First in Class Therapy

Substantial Market Opportunity and Critical Unmet Medical Need

Pursuing Approval of the DefenCath NDA

Compelling Safety & Efficacy Profile

Compelling HEOR and Health Equity Implications



DefenCath is a novel, broad-spectrum, antimicrobial catheter lock solution with the potential to change the standard of care in several large markets – there is no current pharmacologic agent approved to prevent or reduce the risk and incidence of catheter related bloodstream infections (CRBSI) associated with the use of central venous catheters (CVCs)

Taurolidine, the active ingredient, is a new molecular entity with broad spectrum antibacterial and antifungal activity, and two mechanisms of action, that does not lend itself to microbial resistance

DefenCath initially targeted in hemodialysis patients. ~ 80% of patients starting hemodialysis will have a CVC inserted for vascular access ¹, with an average duration of 220 days ², and roughly **25%-33%** will experience a CRBSI ⁶, with a significantly higher mortality rate vs. non-CRBSI HD patients

The Company estimates the inpatient market opportunity at 3mm-5mm 3ml vials per year, and the outpatient opportunity at 30mm-80mm vials per year, where two vials of 3 ml DefenCath would be utilized per catheter

CMS has proposed NTAP (inpatient reimbursement) with a maximum reimbursement per average hospital stay of ~\$17K

Potential to receive 10.5 years of regulatory market exclusivity beginning upon NDA approval; plus IP to 2042

Following an April Type A meeting with the FDA, CorMedix has resubmitted the DefenCath NDA, utilizing its existing CMO and including data from multiple suppliers of heparin API; The NDA has been accepted for filing as a class 2 resubmission with a 6-month review, and a PDUFA target action date of November 15, 2023

The Company intends to provide any necessary support to its existing CMO as it prepares for a potential pre-approval inspection at the facility

LOCK-IT-100 trial of DefenCath demonstrated a 71% reduction in the risk of occurrence of CRBSI in 795 HD subjects ³

Safety profile comparable to the heparin catheter lock control arm, which is the current standard of care designed to preserve catheter patency, but not infections³

HD patients with CRBSIs have 2x more hospitalizations per year, with 4x longer duration of stay ⁴, and 3x higher fatality rate ². HD patients with a CRBSI incur 2x higher per patient hospital cost ⁵, with an estimated 250,000 CRBSIs per year in U.S. ⁶

African Americans make up 17% of the U.S. population but more than 35% of patients undergoing hemodialysis ⁷, disproportionately exposing them to higher risk for CRBSI



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