Defencath™: A potentially new standard-of-care in the prevention of catheter related blood stream infections
Forward-Looking Statements

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Defencath™ is a Novel Product Targeting Substantial Market Opportunities

**Novel Product Addressing a Significant Unmet Need in Multiple Clinical Indications**
- Defencath is a novel catheter lock solution with the potential to change the standard of care in several large markets – no current pharmacologic agent approved to prevent infections associated with central venous catheters (CVCs).
- Defencath is intended initially for CVCs used by hemodialysis patients to reduce the risk of catheter related blood stream infections. Expanded label to be sought for use in catheters used by oncology and total parenteral nutrition (TPN) patients.

**Substantial Market Opportunities**
- Cost for treating all CRBSI episodes and their complications is up to $2.7B – 250,000 CRBSIs per year in U.S.\(^1\)
- Large addressable markets for catheter-lock solutions in hemodialysis setting (~80MM catheter lumen locks per year\(^2\)) and oncology/TPN (~150MM catheter lumen locks per year\(^3\)) in U.S.
- Hemodialysis market can be addressed with a modest sized infrastructure (~50 individuals) given concentration of the dialysis clinics.

**Anticipating Potential FDA Approval in Lead Indication**
- Granted rolling submission and review of NDA by FDA based on data from LOCK-IT-100; NDA filed and granted priority review with February 28, 2021 PDUFA date.
- Fast track and QIDP designations granted by FDA.
- 10.5 years of potential market exclusivity pursuant to New Chemical Entity, QIDP designation and pediatric exclusivity.

**Data Demonstrate Effectiveness and Safety**
- LOCK-IT-100 trial of Defencath demonstrated 71% reduction in the risk of occurrence of CRBSI in 795 hemodialysis subjects.
- Safety profile comparable to heparin catheter lock solution, which is the current standard of care designed to prevent clotting, but not infections.

**Talented and Experienced Management Team**
- Executive management team brings significant relevant commercial and clinical experience from large pharma.
- Leadership team has launched >40 drugs in aggregate at prior companies.

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\(^1\) Becker’s Hospital Review
\(^2\) Market research commissioned by CorMedix from third party firm
# CorMedix Senior Management Team

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<thead>
<tr>
<th>Name</th>
<th>Role</th>
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<tbody>
<tr>
<td>Khoso Baluch</td>
<td>Chief Executive Officer</td>
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<tr>
<td>Matt David, MD</td>
<td>EVP and Chief Financial Officer</td>
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<tr>
<td>Phoebe Mounts, PhD, JD</td>
<td>EVP and General Counsel</td>
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<tr>
<td>Paul Chew, MD</td>
<td>Chief Medical Officer</td>
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<tr>
<td>Jack Armstrong</td>
<td>EVP Technical Operations</td>
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<tr>
<td>Elizabeth Masson Hurlburt</td>
<td>EVP &amp; Head of Clinical Operations</td>
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Targeting a Substantial Commercial Market Opportunity

- No pharmacologic agents approved in the U.S. for the prevention of CRBSI in central venous catheters
- Total annual cost in U.S. for treating all CRBSI and their complications up to $2.7B
- Multiple organizations are focused on reducing CRBSIs – CDC, NIH, CMS, IDSA, ASCO, ASPEN, among others

- 2025 estimate of ~80MM catheter lumen locks and growing
- Meets eligibility requirements for add-on payment (TDAPA) outside of the ESRD bundle for at least the first two years

- 2025 estimate of ~136 million catheter lumen locks
- Immunocompromised patients at elevated risk of CRBSIs
- ~95% of patients treated for their cancer in out-patient settings, most with favorable ASP+ reimbursement

- 2025 estimate of ~13 million catheter lumen locks
- Patients receiving TPN at home are at very high risk of infections

* TDAPA: Transitional Drug Add – On Payment Adjustment
** Source: Market research commissioned by CorMedix from third party firm
***Note: Centers for Disease Control and Surveillance (CDC), National Institutes for Health (NIH), Centers for Medicare and Medicaid Services (CMS), Infectious Disease Society of America (IDSA), American Society of Clinical Oncology (ASCO), American Society of Parenteral and Enteral Nutrition (ASPEN)

Estimated 2025 Market for Catheter-Lock Solutions
(lumen locks, annually)

- Hemodialysis: 80
- Oncology: 136
- TPN: 230
- Total: 446

Hemodialysis Oncology TPN Total

Estimated 2025 Market for Catheter-Lock Solutions**
(lumen locks, annually)
Defencath™/Neutrolin® is an Anti-Bacterial and Anti-Fungal Catheter Lock Solution Designed to *Prevent* CRBSIs and Clotting

- Used to fill catheter lumens when they are not in use to prevent microbial growth and clotting

**DEFENCATH / NEUTROLIN PROPRIETARY FORMULATION**

- Heparin 1000 U/ml (anti-coagulant)
- Taurolidine – 1.35% (anti-infective)
- Citrate – 3.5% (pH buffer)

**NEUTROLIN/DEFENCATH REGULATORY STATUS**

- In the EU, *Neutrolin* is regulated as a medical device and is CE Marked for commercial distribution in the EU and other jurisdictions
- In the US, *Defencath* is regulated as a New Drug; New Drug Application has been submitted and accepted for filing by FDA
- For medical professionals, catheter instillation of *Neutrolin/Defencath* is consistent with current practice of using heparin, but with an added benefit of an anti-infective
- Broad antimicrobial activity, including gram-negative and gram-positive bacteria, multi-drug resistant bacteria, as well as fungi
- No demonstrated development of antimicrobial resistance in laboratory studies
LOCK-IT-100 – Pivotal Clinical Trial Design

**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 minimum treatment effect of 55% vs. the control arm

**OBJECTIVE**
- 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**
- Time to occurrence of CRBSI

**SECONDARY ENDPOINTS**
- Loss of catheter patency
- Catheter removal for any reason
Phase 3 LOCK-IT-100 – Topline Results

- Primary endpoint met – highly statistically significant efficacy
- Secondary safety endpoints met - no statistically significant differences between Defencath (D) & Heparin (H) control arm for loss of catheter patency and catheter removal

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<thead>
<tr>
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<th>Interim Analysis</th>
<th>Full Study</th>
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<tr>
<td>Total CRBSIs (D / H)</td>
<td>28 (6 D / 22 H)</td>
<td>41 (9 D / 32 H)</td>
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<tr>
<td>Total Subjects</td>
<td>653</td>
<td>795</td>
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<tr>
<td>Defencath Reduced CRBSIs</td>
<td>72%</td>
<td>71%</td>
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<tr>
<td>Defencath (heparin control) Event Rates*</td>
<td>0.136 (0.491)</td>
<td>0.133 (0.465)</td>
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<tr>
<td>p-value</td>
<td>0.0034</td>
<td>0.0006</td>
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*Event Rate is per 1,000 Catheter-Days
Phase 3 LOCK-IT-100 – Conclusions

01
LOCK-IT-100, a landmark study, showed that in ESRD subjects with hemodialysis via a central venous catheter, Defencath catheter lock solution significantly reduced catheter-related bloodstream infections by 71% \( (p=0.0006) \) in 795 patients (9 D, 32 H).

02
Compared to heparin, there was NO statistically significant difference in either catheter removals for any reason \( (p=0.42) \) or loss of catheter patency \( (p=0.12) \).

03
Treatment-emergent serious adverse events were infrequent and similar between Defencath and Heparin arms.
Defencath Regulatory Status

- FDA granted rolling submission and review of Defencath New Drug Application
  - Ongoing dialogue with FDA on submitted modules

- FDA accepted submitted NDA for filing
  - FDA had 60-day period to review for completeness and to make filing decision

- Priority review granted
  - Eligibility pursuant to Fast Track and Qualified Infectious Disease Product designations
  - Priority review goal 6 months vs. standard review period of 10 months
  - February 28, 2021 PDUFA date

- Also requested NDA approval pursuant to Limited Population Pathway for Antibacterial and Antifungal Drugs, if needed to provide FDA with additional flexibility for NDA approval based on the single study of LOCK-IT-100

- Preliminary discussions with FDA for use in additional patient populations using CVCs (oncology/TPN)
  - Now planning as post-approval studies, including pediatric hemodialysis patients to extend marketing exclusivity by 6 months
Defencath Pricing Will be Supported by its Clinical Benefit and Economic Benefits to the Healthcare System

Several factors currently being assessed to derive pricing include:

1. In the US, will be the first approved antimicrobial catheter lock solution
2. Facilities and patients involved in at-risk arrangements involving coordination of care
3. Clinical benefit of preventing life-threatening infections
4. Reductions in CRBSIs (inpatient and outpatient costs)
5. CRBSI-related complications reduced
6. Antibiotic use and potential for microbial resistance decreased
7. Fewer missed dialysis days

- Pricing will be supported by the offsets Defencath provides to the broad economic burden on the U.S. healthcare system linked to CRBSIs
- Preliminary work completed; detailed analysis ongoing through 2020
Medicare (CMS) Accounts for ~90% of ESRD Reimbursement and is Very Focused on Quality of Care

**Coverage**
- Medicare coverage kicks in
  - Ensures dialysis care for all patients
  - Includes commercial insurance after a period of time

**Quality of Care Measures**
- Medicare rates all dialysis facilities on quality of care measures that are publicly available
- Measures include infection rates, hospitalizations
- Medicare is incorporating additional patient ratings on each dialysis facility to drive additional quality

**Medicare Advantage**
- Medicare Advantage (MA) becomes an available choice for all dialysis patients starting in 2021
- ESRD programs through MA typically provide additional covered services

Medicare has a special reimbursement program to encourage innovation called **TDAPA – Transitional Drug Add-on Payment Adjustment**

**More Choice**

**Payer Mix for Dialysis Patients**
- Medicare FFS: 36%
- Medicare & Medicaid Dual Eligible: 19%
- Medicare Advantage: 19%
- Group Commercial: 7%
- Other Secondary Coverage: 1%
- Other Primary Coverage: 27%
Defencath Reimbursement Opportunity Through TDAPA

* Under new regulations effective January 2020, New Chemical Entities (NCEs) are eligible for CMS reimbursement outside the bundle under the TDAPA* program

- The intent of the TDAPA is to facilitate beneficiary access to certain new renal dialysis drugs or biological products by allowing payment for these products while the necessary utilization data are collected
- CMS will pay for the drug or biological using a TDAPA for at least 2 years – If the injectable or intravenous product is used to treat or manage a condition for which there is not an existing ESRD PPS functional category
- If approved under TDAPA, reimbursement of Defencath would be calculated based on its average selling price.

**Drugs with TDAPA Designation**
- Parsabiv (Amgen)
- Sensipar (Amgen)

*** Both Amgen products received TDAPA extension beyond the 2 year mark
- Parsabiv remains in TDAPA
- Sensipar was terminated when generic became available

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* TDAPA (Transitional Drug Add – On Payment Adjustment) allows for facilitation of beneficiary access to certain qualifying, new injectable or intravenous products by allowing payment for these drugs and biologicals while the necessary utilization data is collected.
** ESRD PPS (End Stage Renal Disease Prospective Payment System)
*** Frequent catheter use for administration of drugs
CorMedix Believes Defencath is Eligible for and Will Obtain TDAPA

Highlights of Rationale to Support TDAPA

- FDA Fast-Track Designation
- FDA Designated as Qualified Infectious Disease Product (QIDP)
- No standard of care has been established to prevent CRBSIs in hemodialysis patients
- Prevention is important as chronic use of anti-infectives increase potential for development of drug resistance
- Meets criterion of being a new renal dialysis product used to treat or manage a condition associated with ESRD
- Infections are the 2nd leading cause of death in patients with ESRD and CVCs are a significant risk factor for infection-associated mortality
Commercial Execution Can Be Accomplished With a Highly Focused Organization

An initial commercial organization of ~50 people can provide adequate coverage for launch into hemodialysis:

- There are ~7,600 dialysis facilities, ~10,000 nephrologists
- However, 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 is laying the groundwork for building a commercial team to prepare for a launch in HD in 2021

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

The geographic concentration of ESRD along with the clear identification of dialysis facilities and corporate owners allows for targeting and efficient deployment of resources (sales reps, medical affairs and market access)
Label Expansion Into Other CVC Areas Provides Opportunities; Oncology has Compelling Dynamics

- There are multiple natural extension opportunities for Defencath beyond hemodialysis catheters
  - Among these, Oncology represents a compelling market opportunity\(^1\)
    - Largest number of catheter locks
    - Immunocompromised patients – risk for CRBSI can be 4.5x higher than in hemodialysis patients
    - Potential to avoid delays in chemotherapy and prolonged hospital stays
    - High oncologist interest
    - Favorable pricing dynamics
  - CorMedix aims to obtain NDA approval Defencath in hemodialysis patients and conduct studies for oncology and TPN in a post-approval setting (safety data focus)

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\(^1\) Source: Market research commissioned by CorMedix using a third party
Manufacturing Overview: Supply Chain Substantially Completed; Launch Quantities in Production

- Successfully concluded technical transfer and validation of the drug product manufacturing process, which has enabled production at 2 different manufacturing locations
  - Company has DMF for taurolidine; production process has been validated
- API (taurolidine and heparin) sourced from U.S./European manufacturers under contract and is shipped to drug product manufacturer, located in Europe
  - Multiple heparin suppliers available for sourcing
  - No Chinese-sourced heparin in supply chain
- Drug product manufacturer produces unlabeled vials in bulk packaging and these are shipped to U.S. for labeling and packaging; stored to be sold by 3PL
- Launch quantities are already in production
- Additional CMO, likely U.S.-based, anticipated for drug product manufacturing; required to meet anticipated demand
- Costs of production, shipment, and labelling/packaging expected to result in gross margins typical of pharmaceutical products
Marketing Exclusivity and Intellectual Property

**MARKET EXCLUSIVITY**

- Upon approval, 10.5 years of potential market exclusivity
- Designated an Investigational New Drug by FDA
- New Chemical Entity (NCE) Status – 5 years of exclusivity
- Designated as Qualified Infectious Disease Product (QIDP) – additional 5 years of exclusivity
- Approval for pediatric use would provide additional 6 months of exclusivity

**INTELLECTUAL PROPERTY PORTFOLIO**

- Patent portfolio consists of:
  - 7 issued U.S. patents and 17 pending U.S. patent applications
  - 14 issued foreign patents and 45 pending foreign patent applications
- Additional patent applications to be filed to cover any additional related subject matter developed
Financial Highlights

**KEY STATISTICS**

- Exchange: NYSE American (CRMD)
- Common Stock: 31.2 million shares as of 8/6/2020
- Market cap: ~$150 million

**BALANCE SHEET**

- Cash: $22.4 million as of 6/30/2020
- Pro forma Cash*: $43.9 million as of 6/30/2020
- Debt: None

* Inclusive of net proceeds from July 2020 financing
CorMedix Key Highlights

- **Defencath is a Novel Product Addressing a Significant Unmet Medical Need**
- **Anticipating Potential FDA Approval in Lead Indication of Hemodialysis**
- **Potential for 10.5 Years of Market Exclusivity**
- **Data Demonstrate Effectiveness and Safety for Preventing CRBSI in Hemodialysis**
- **Substantial Market Opportunities in Hemodialysis; Further Upside in Oncology and TPN Markets**
- **Senior Leadership with Significant Experience Bringing Drugs to Market**
Thank you

A potentially new standard-of-care in the prevention of central venous catheter infections, decreasing hospitalizations and death.

September 2020