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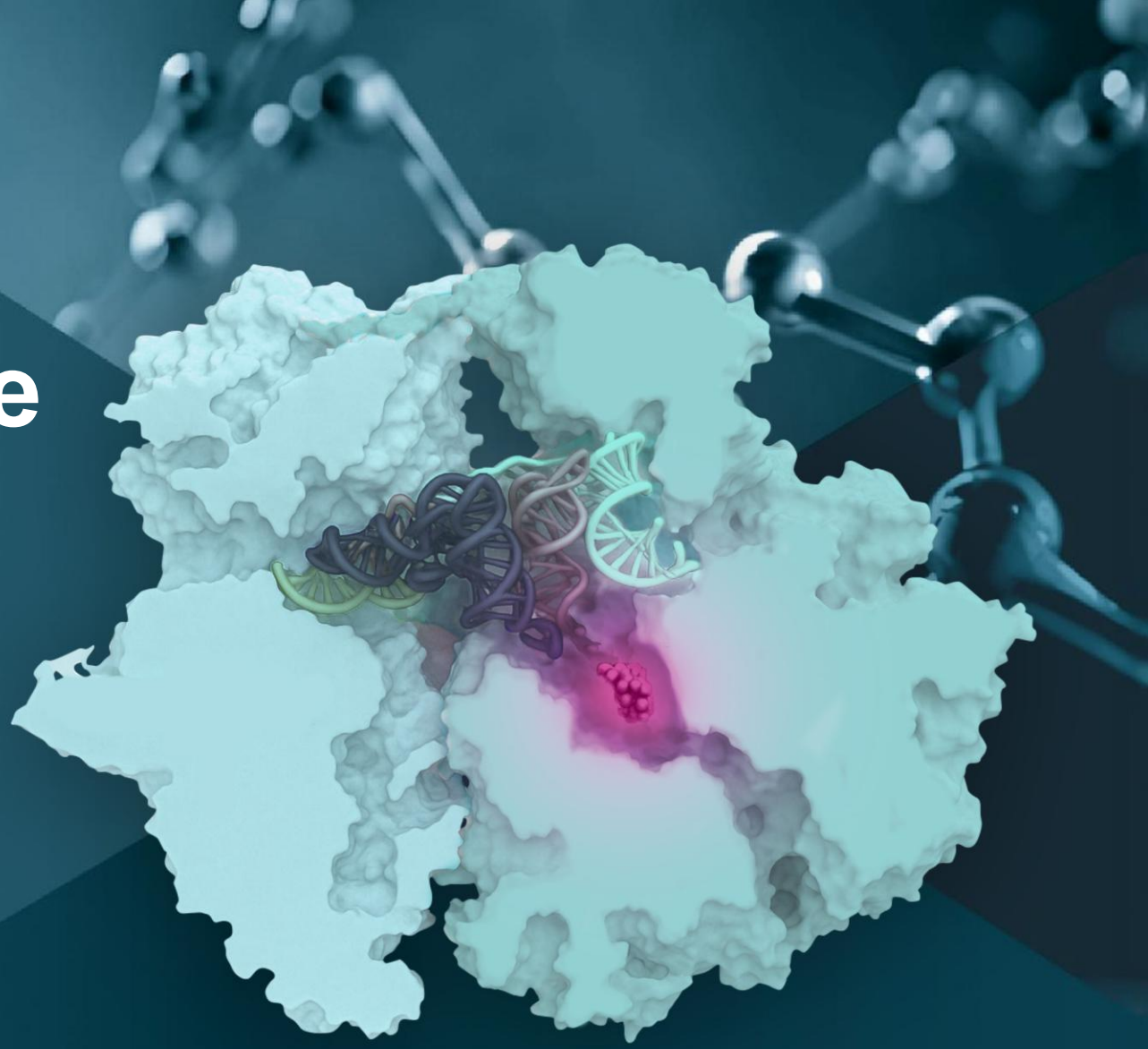
Target Product Profile utility in biotech



Obadiah Plante PhD, *SVP and Head of Research, Kinvard Bio*

11th September 2025

Kinvard Bio is building upon world-class science, addressing the most challenging bacterial infections…

…founded upon groundbreaking research and a prestigious scientific heritage

- **Founding scientist and inventor:** Pr. Andrew Myers (Tetraphase & Macrolide Pharmaceuticals).
- **I.P. exclusively licensed** from the Myers lab, Department of Chemistry and Chemical Biology at Harvard University.

KINETICOS LIFE SCIENCES

Funded by Kineticos AMR Accelerator Fund I (KAMRA I), incubated by the Kineticos Foundry program.

CARB-X
Combating Antibiotic-Resistant Bacteria

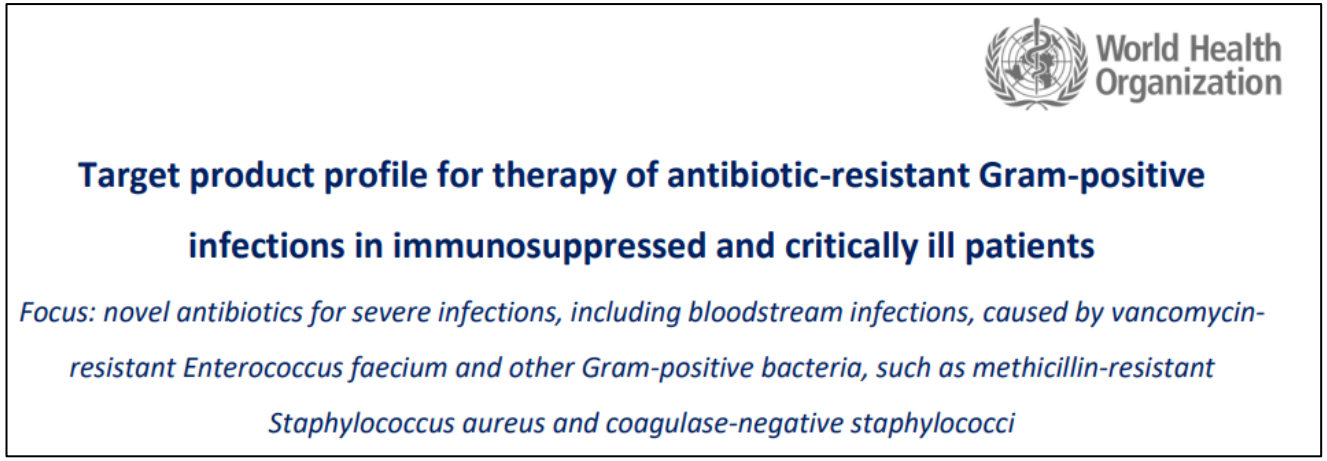
$2.7M non-dilutive follow-on funding to support Lead Optimization (July 2025).

$1.2M 'seed grant' (Myers lab, Feb. 2024).

	INDICATION	ROUTE OF ADMINISTRATION	DEVELOPMENT STAGE
KV-001	Gram-Negative Infections HABP/VABP, cUTI	Oral and IV	Lead Optimization
KV-002	Gram-Positive Infections CABP/ABSSSI	Oral and IV	Lead Optimization
KV-003	Chronic Respiratory Infections NCFBE, CF, NTM-LD	Oral	Discovery

There are a number of publicly accessible TPP resources…

WHO resources


World Health Organization

Target product profile for therapy of antibiotic-resistant Gram-positive infections in immunosuppressed and critically ill patients

Focus: novel antibiotics for severe infections, including bloodstream infections, caused by vancomycin-resistant Enterococcus faecium and other Gram-positive bacteria, such as methicillin-resistant Staphylococcus aureus and coagulase-negative staphylococci

Tips

- **Think about 'what next?'**
- **Don't forget to talk to potential partners and seek input on their TPP focus**
- **A partnering strategy is a critical element of your development pathway route to the patient (commercialization)!**

TPPs are essential to guide pharmaceutical product development

- **Many metrics are established by global health agencies (ex. WHO)**
  - **Can be used as a guide, but important to develop a TPP specific to your product *and* modality**
- **TPPs are essential to drug developers and funders(!)**
- **Early consideration of TPPs builds credible teams and products**
- **TPPs are a 'must have' in any and all programs, no matter how early**

Ref: whoantibacterialtpps_publicconsultation_13aug25.pdf

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Draft WHO TPP guidance

TPP for therapy of antibiotic-resistant Gram-positive infections

Short form Target Product Profile		
Attribute	**Minimal**	**Ideal**
Indications for use	Severe infections, including BSIs, in immunosuppressed and critically ill patients, caused by antibiotic resistant Gram-positive bacteria.	All criteria in the minimal TPP, plus more complicated infections, such as intravascular catheterrelated infections and native or prosthetic valve endocarditis
Patient Population	Hospitalized patients with immunosuppression and severe community- or hospital-acquired infections	Critically ill patients, including patients treated in intensive care units (ICUs) and receiving haemodialysis
Key pathogens	Activity against Gram-positive pathogens, including vancomycin resistant *E. faecium,* and other enterococci and staphylococci with resistance to vancomycin and β– lactams (VRE, MRSA and methicillin-resistant coagulase negative staphylococci). No cross-resistance to currently used antibiotics, and low propensity for resistance development	S[illegible]as minimal TPP, and activity against strains with acquired resist[illegible]ce to linezolid and daptomycin
Treatment Duration	7-10 days	5-7 days
Route of Administration	IV	Oral and IV
Regimen	1-4x daily	1-2x daily
Efficacy	Proven clinical efficacy in randomized con[illegible]ed trials for severe Gram-positive infections, including patients with BSIs, immunosuppression, and infections caused by pathogens resistant to vancomycin and/or beta-lactams	Same criteria as minimal TPP and with demonstrated efficacy for more complicated infections, and optimized dosing for PK/PD target attainment in critically ill patients.
Safety	Any adverse events are reversible and manageable in the targeted patient population	Same as minimal TPP, plus no need for routine therapeutic drug monitoring

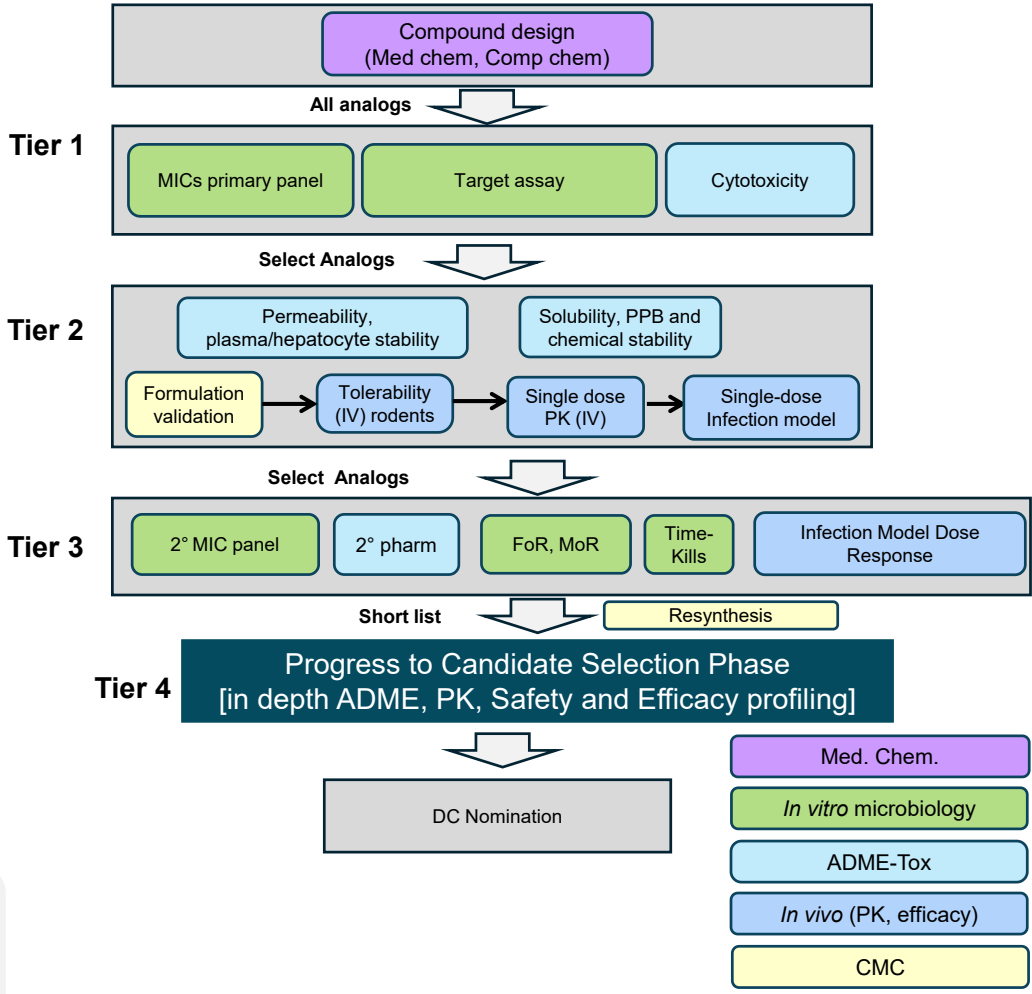
Driving discovery: The Target Candidate Profile is an essential discovery program tool guided by TPP

TCP criteria for early research programs

TCP defines critical attributes specific to the designed product that addresses the needs of the TPP

For example:

- Antimicrobial spectrum
- Avoidance of specific resistance mechanisms
- Acceptable potency and efficacy (predicted human dose)
- Stability
- Specificity
- Rate of clearance
- Solubility
- Predicted human dose



The TCP drives selection and prioritization of compounds – 'screening cascade' - during the discovery phases

Focusing discovery efforts, delivering the candidate that will treat the disease in the target patient population

Focus and communication: Vision and objectives supporting funding and partnership strategy

Developing a candidate to align with the TPP

- **Pathogen spectrum:** Coverage of Gram-positive bacteria and pathogens implicated in CABP / ABSSSI.
  Avoidance of pre-existing resistance mechanisms that reduce effectiveness of SOC antibiotics.
- **ADME/Tox:** Avoidance of DDIs, establish therapeutic index (based on risk-benefit profile of drug).

  PK/PD: establish driver and target attainment.
  Human dose prediction: how much to dose and how often.
- **Route of administration:** Oral dosing essential (IV/PO upside): Establish and optimize for oral bioavailability

Important to profile against and potential clinical comparators

Communicate to funders and partners

Diligence over months to years

Non-dilutive funding

CARB-X
Combating Antibiotic-Resistant Bacteria

TPPs ensure alignment of objectives

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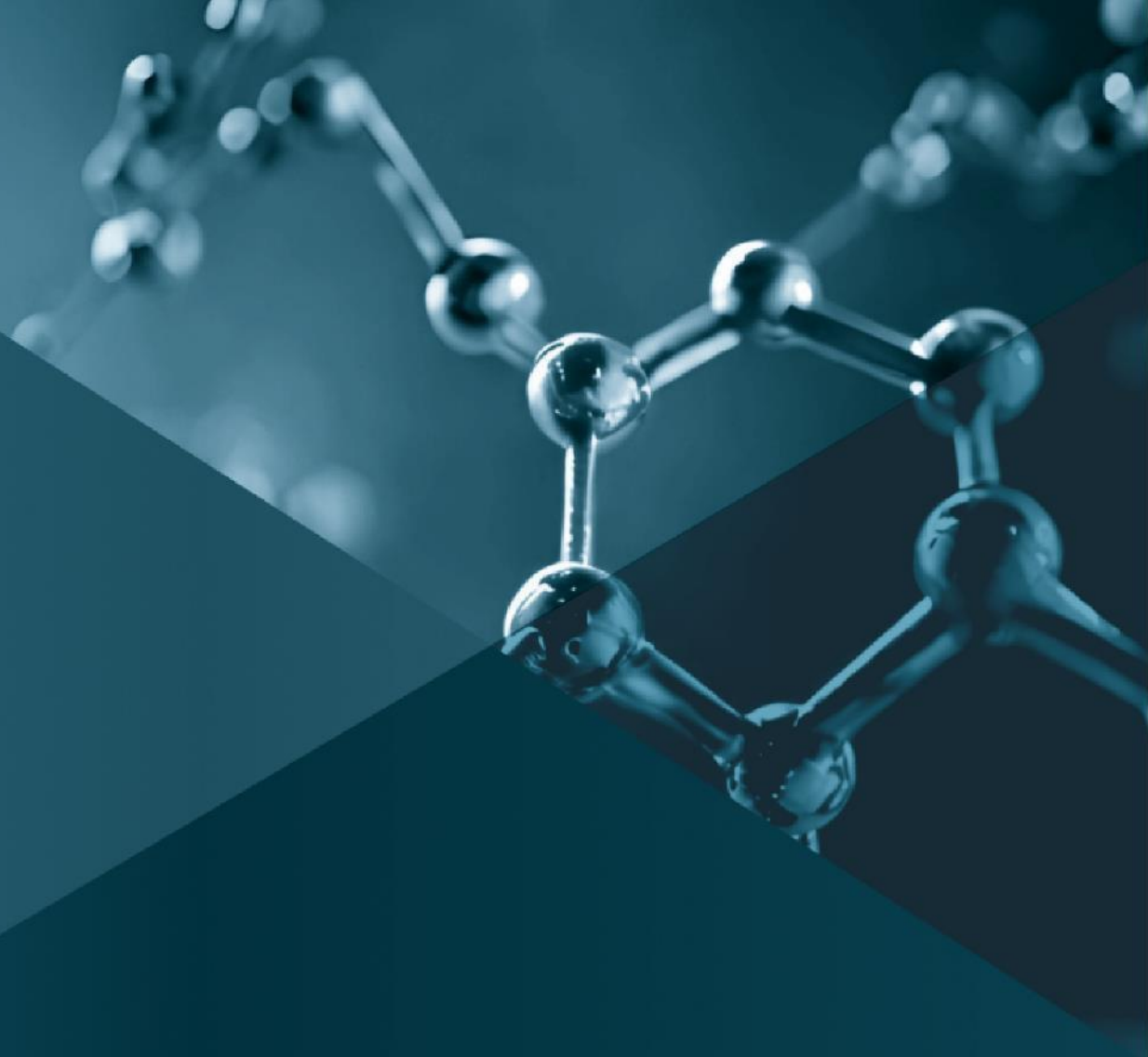

Thank You!

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