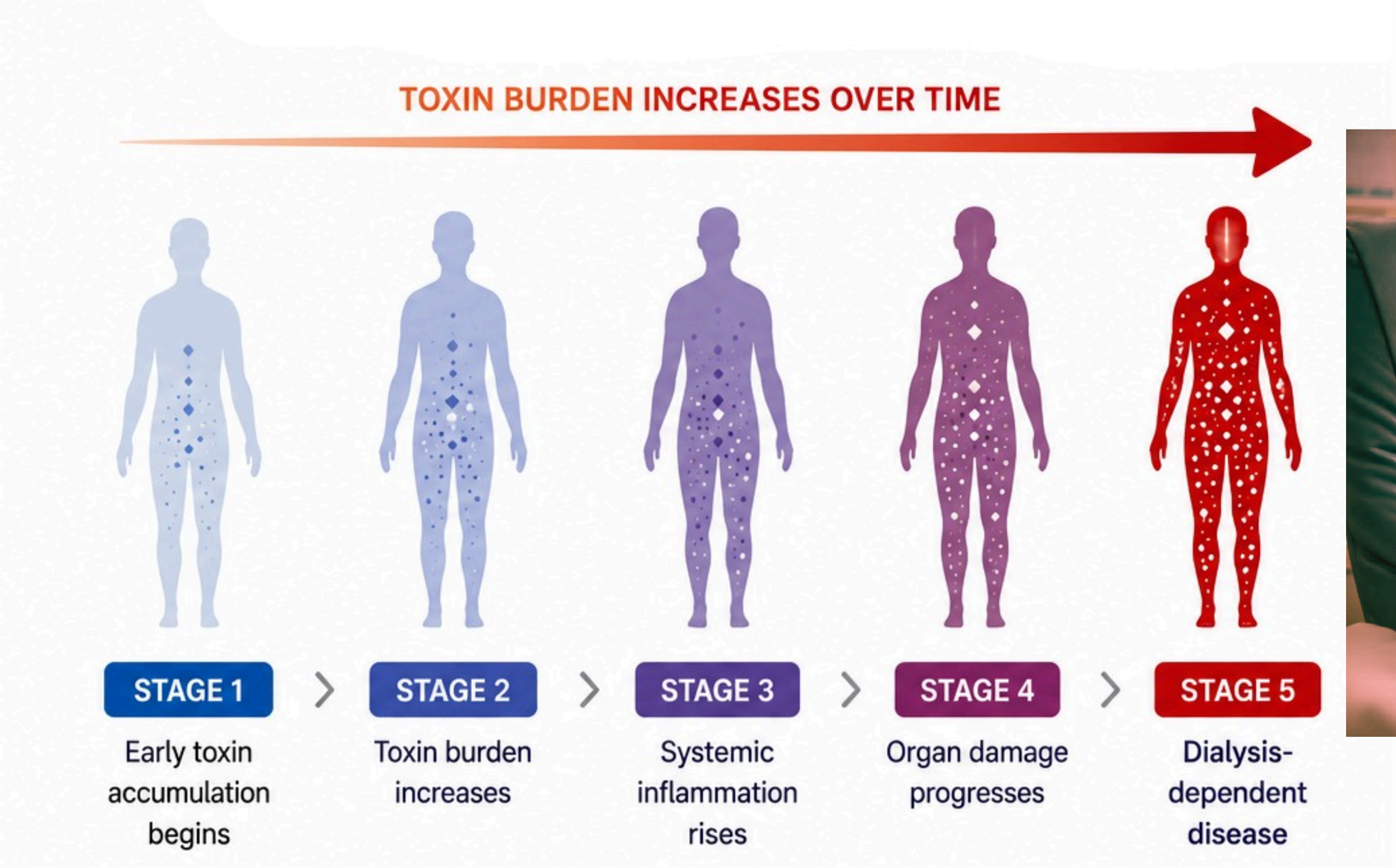
TheraT: Transforming Kidney Health

Improving the lives of CKD patients through gastro-intestinal modulation

THERA T



850M people live with Chronic Kidney Disease

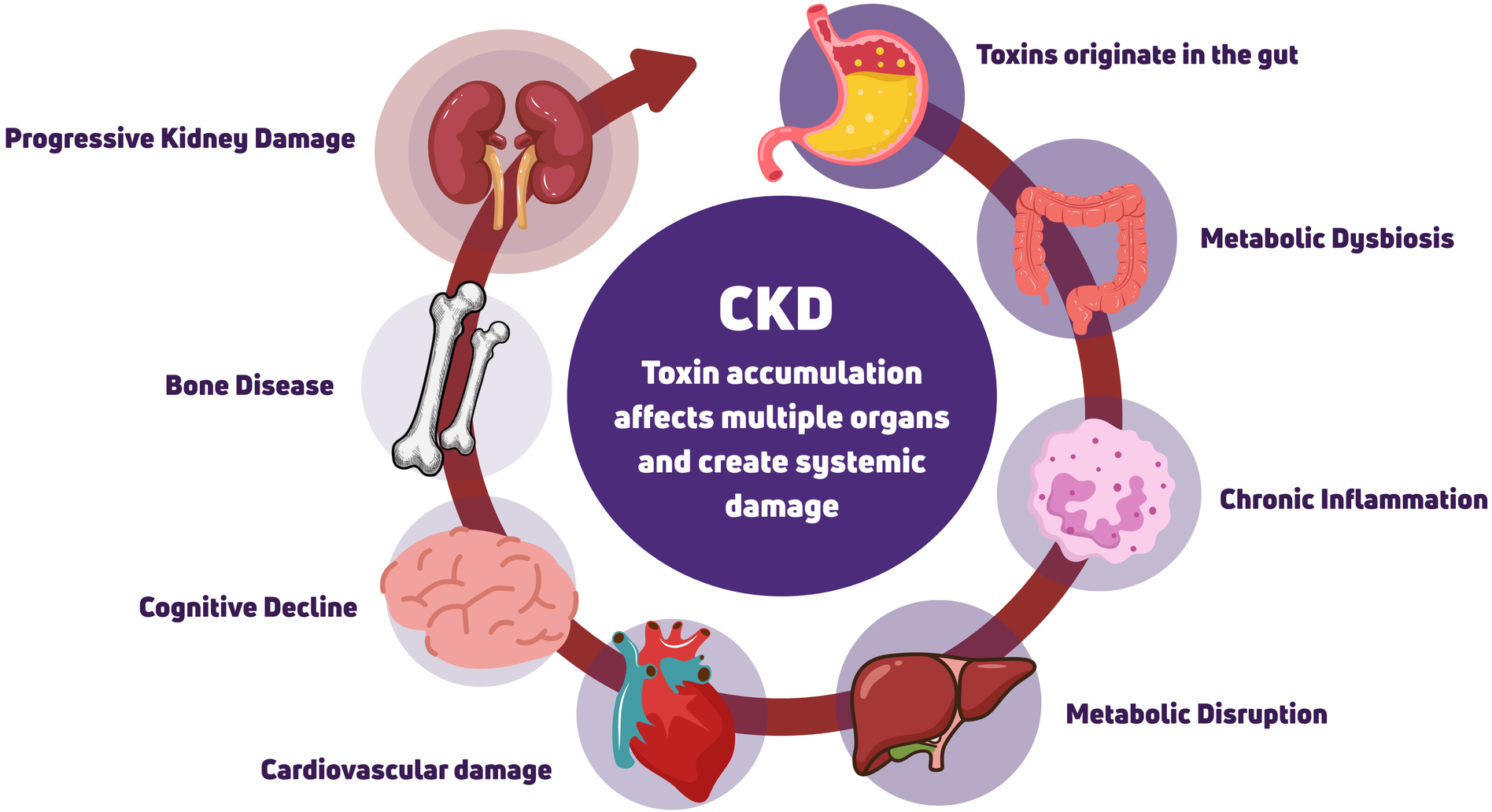




% CKD population	~65%	~25%	~5%	~1%

Dialysis costs 1 % of the government budget (~60B/year)

Toxin accumulation is a downstream consequence that compounds the disease



We created bubbles that capture toxins before systemic damage occurs

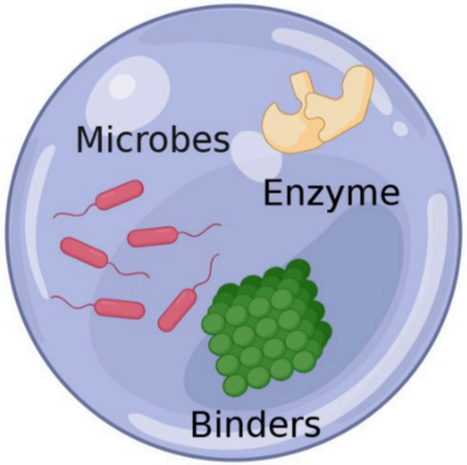
1. Get TheraT prescription from nephrologist



2. Taken orally in any liquid of your choice

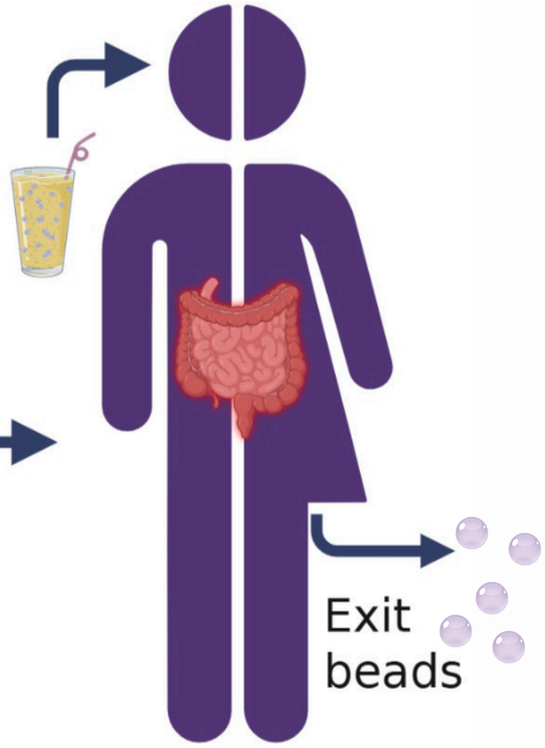


3. The bubbles protect and densify microbes, enzymes, and binders that remove toxins from gut.

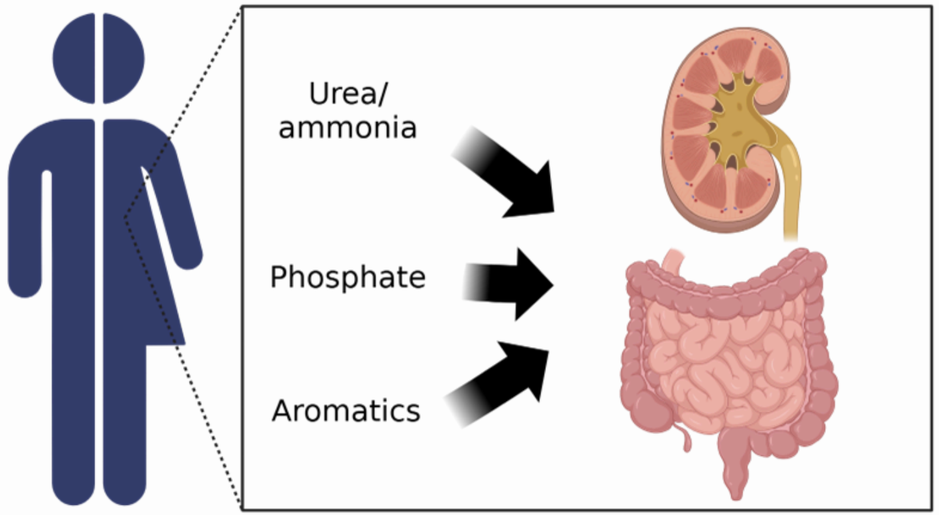


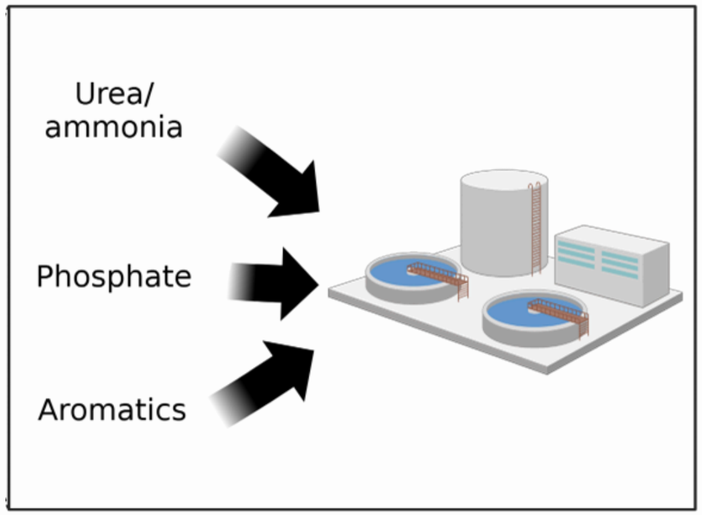


4. Bubbles excreted with toxins



TheraT technology is inspired in proven science



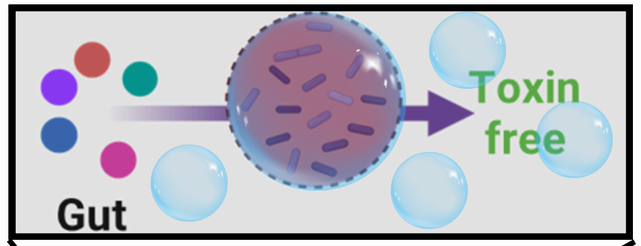


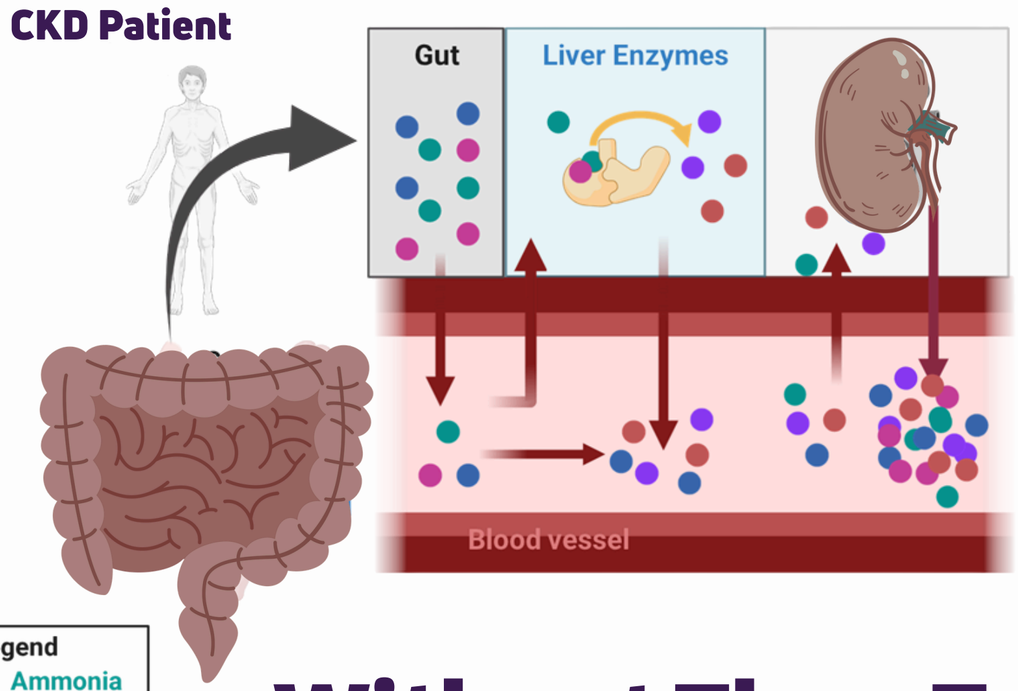
TheraT toxin capture has been proven at a large scale

Translating proven approach into a safe and ingestible format

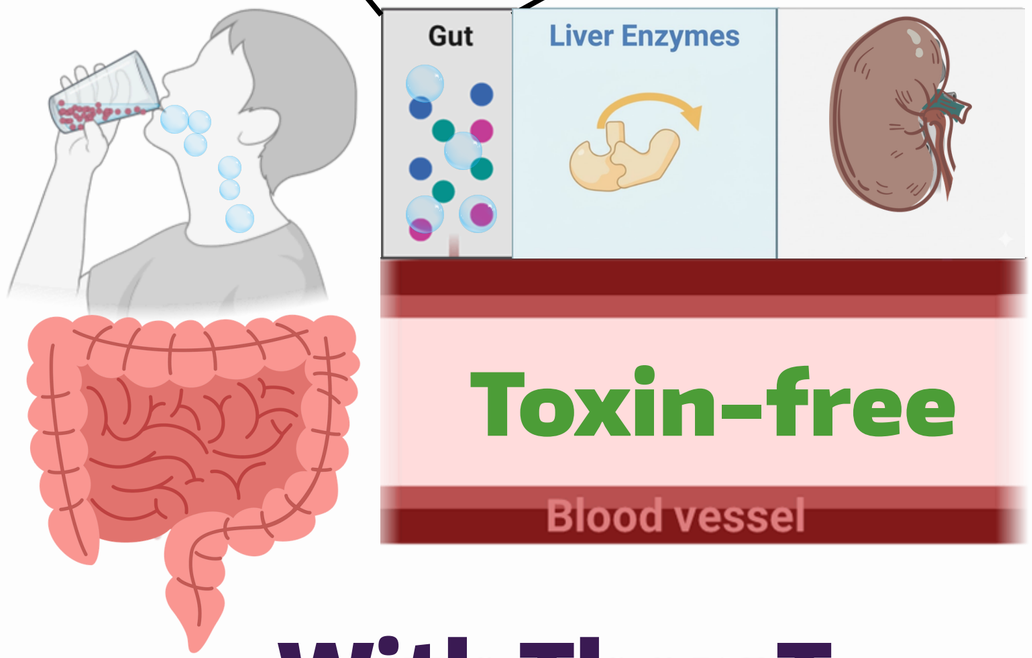
TheraT can prevent toxins from entering in the blood

We can make the GI track work as a water treatment plant to capture these dangerous toxins and take the burden off the kidneys



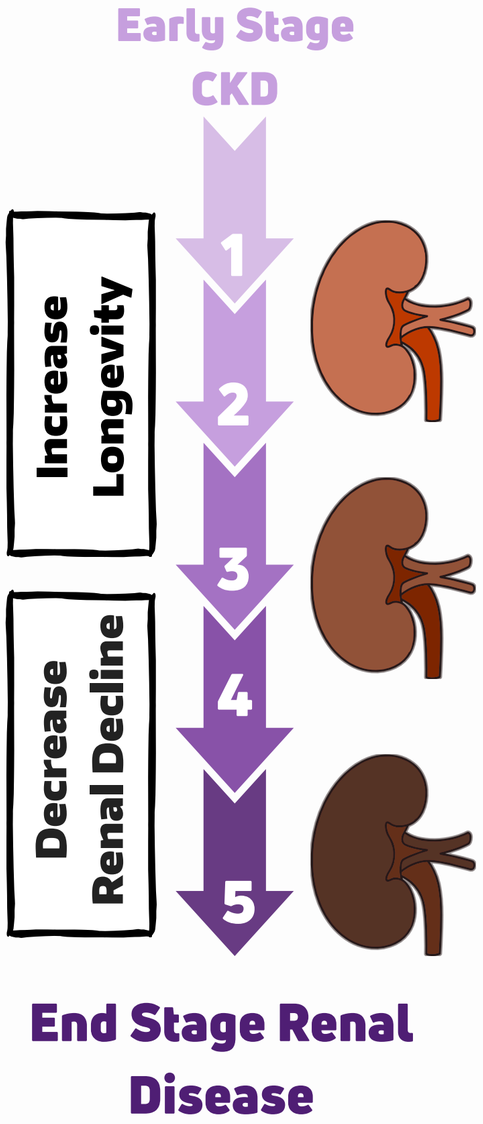


Without TheraT



With TheraT

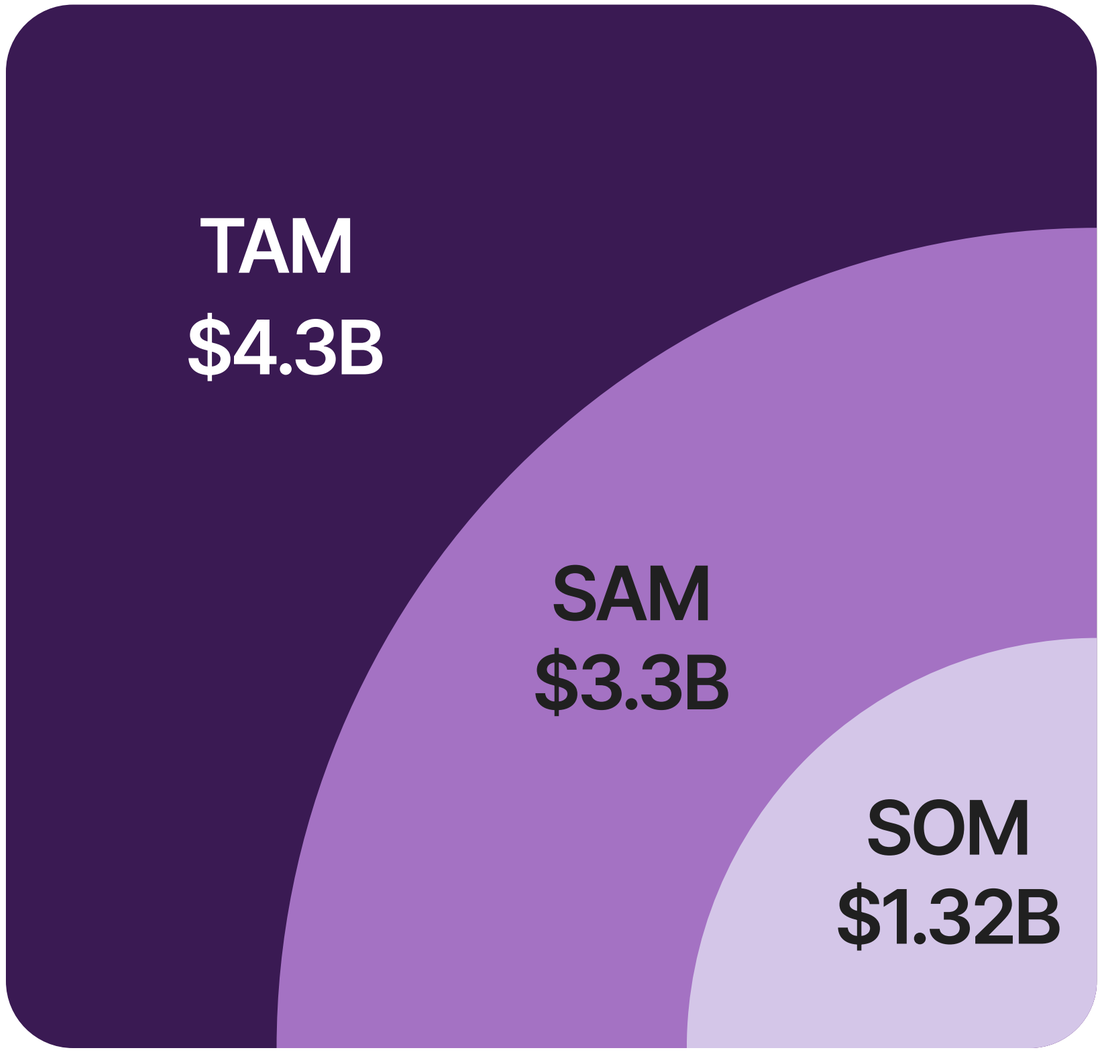
TheraT could improve health outcomes for patients



- Lower systemic toxin accumulation
- Slow progression of kidney disfunction
- Extend transplant lifespan
- Slow progression on secondary disease burden
- Reduce dialysis frequency or session duration

CKD=Chronic Kidney Disease

TheraT will start as a phospate regulation therapy



TAM - $4.3 B HYPERPHOSPHATEMIA

- 25% of US dialysis patients remain above their phosphorus target
- 45% of hemodialysis patients reported skipping phosphate binder pills at least once in the prior month

SAM - $3.3 B

- 516,837 U.S. dialysis patients as of March 2025
- 80% of dialysis patients require some form of phosphate-lowering therapy = 516,837 * 0.8 = 413,469 patients
- Target Price: **$8000 per year** per patient
- 413,469 patients * $8000 = $3.3B

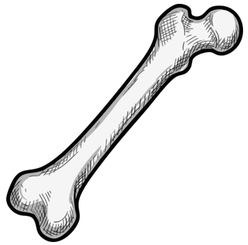
SOM - $1.32B

- **40% penetration** to achieve our peak revenue target
- 165,387 patients * $8000 = $1.32B

TheraT actively removes phosphate from the gut

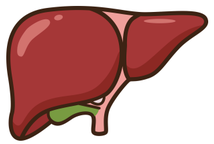
We validated phosphate removal from the blood in animal studies.

Complications of high phosphate



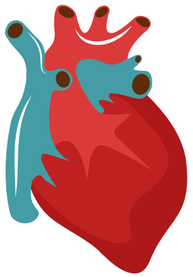
Bone disease

Weakened, brittle bones with increased fracture risk



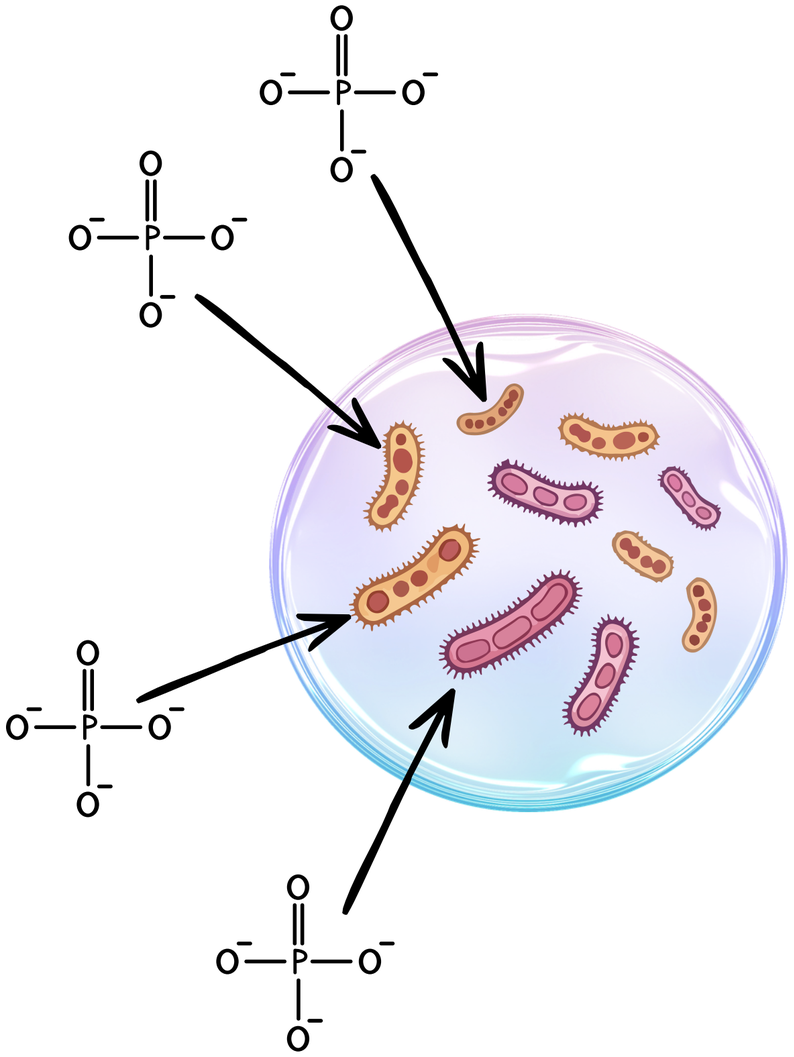
Metabolic Disruption

Oxidative stress and impaired energy metabolism

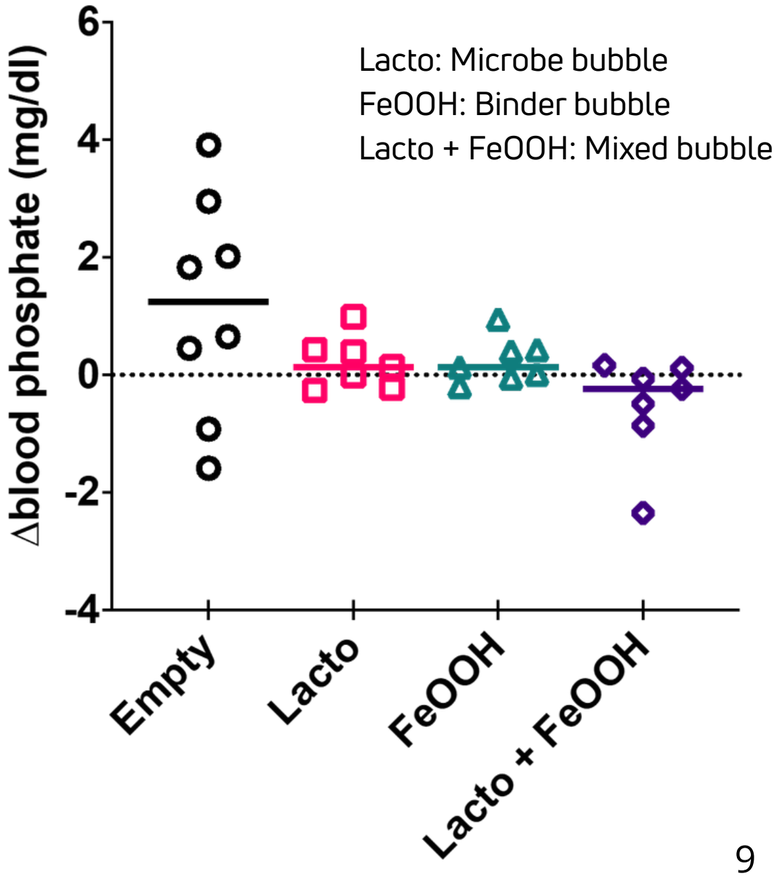


Cardiovascular calcification

2× higher adjusted mortality risk



↓ Blood phosphate in vivo



We have designed it to improve patient's outcomes

Feature	***Sevelamer*** *(Renvela)*	***Other binders*** *(lanthanum, ferric citrate, Ca acetate)*	***Tenapanor*** *(Xphozah)*	***TheraT***
Efficacy	△	△	△	?
Toxin capture mechanism	△	△	△	✓
Dosage form	⊘	⊘	⊘	✓
Non-systemic exposure	✓	△	✓	✓
GI side effects	⊘	⊘	⊘	✓

✓ Fully Effective △ Partially Effective ⊘ Non-Effective

Our regulatory strategy is to commercialize as a FDA approved therapy

Regulatory Path

TheraT is a combination product, where the the active pharmaceutical ingredients are living organisms, which makes it fall under the **Live Biotherapeutic Product (LBP)**

Clinical Trials

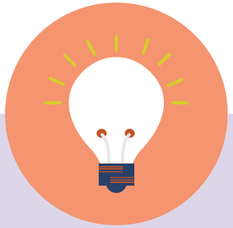
Human trials to prove phosphate reduction in the blood. It is a validated surrogate accepted by the FDA, reducing trial costs and time.

Precedents

Sevelamer and Tenapanor

Unlocks

Platform designation and validated delivery system



Why not a Nutraceutical?

A nutraceutical designation forfeits disease treating label claims, prescription reimbursement, and biotech investors.

TheraT removes hard-to-treat PBUT toxins

Complications of high PBUTs



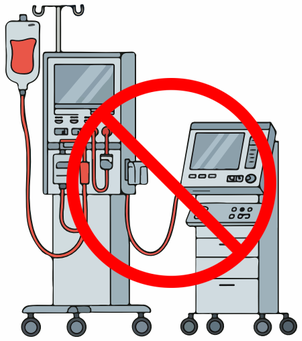
Cognitive Decline
Higher rates of cognitive impairment (20%-70%)



Cardiovascular damage
Increased risk of hospitalization or death

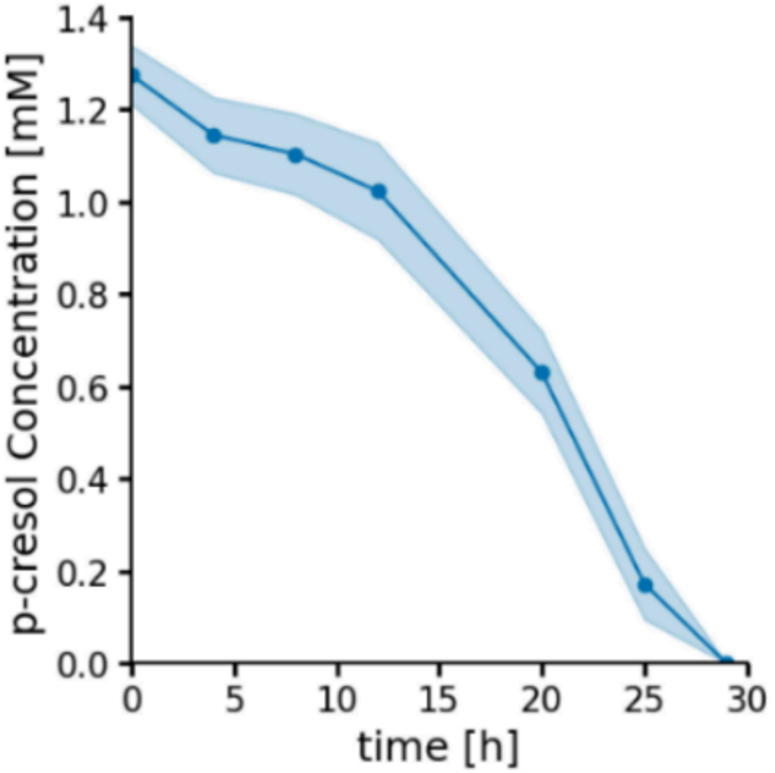


Kidney Damage
Tubular necrosis and collagen scarring

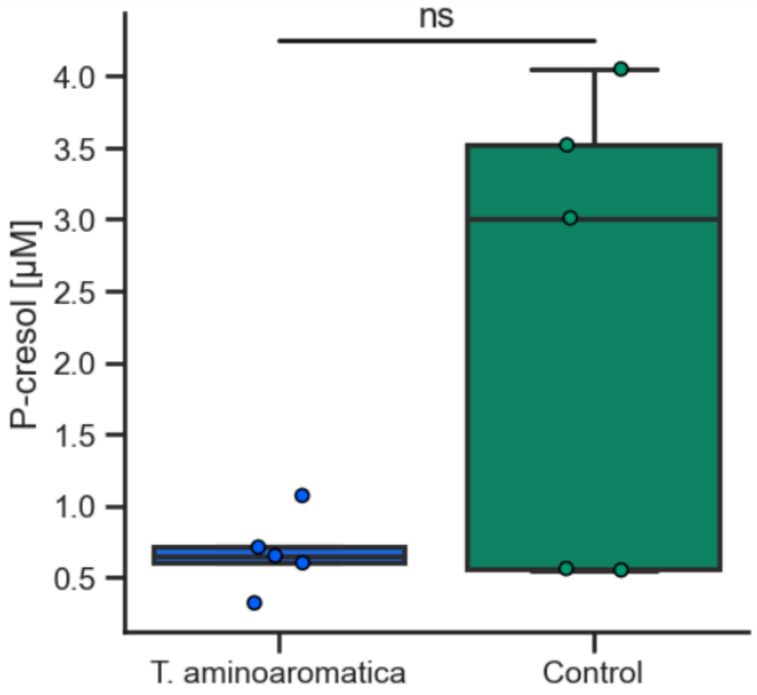


PBUTs are poorly removed by dialysis.

Lab Results



Pre-clinical In vivo

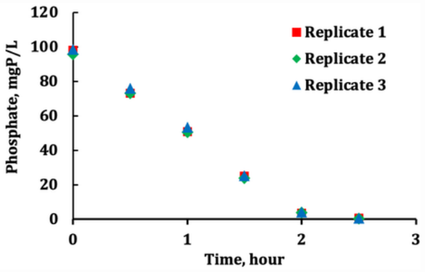


PBUT = Protein Bound Uremic Toxins

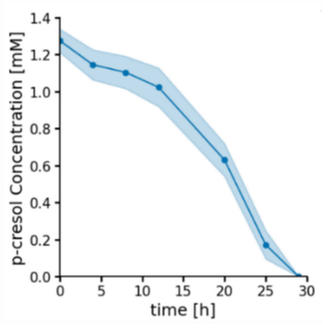
TheraT adapts to each patient's toxin profile

We have other toxins in the R&D pipeline with exciting applications

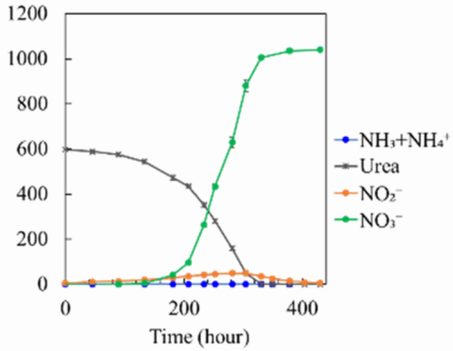
Phosphate



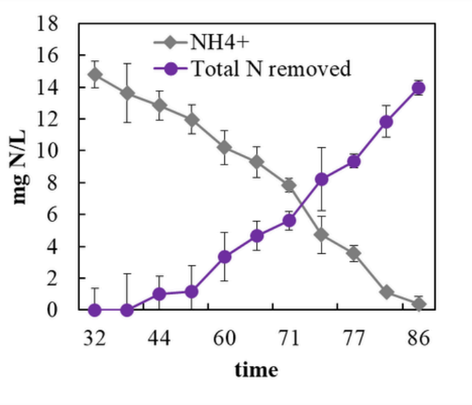
PBUTs



Urea

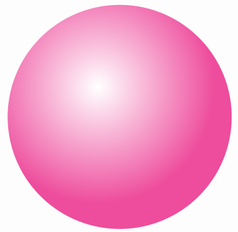


Ammonia











- Mix and match solution depending on patients blood panel results.
- Expand to other toxins, diseases, and applications.

TheraT can expand to address a full CKD joruney

Phosphate

Hyperphosphatemia

Improve patient health outcomes by improving efficacy, pill burden, and patient adherence.

PBUTs

Slow CKD progression

AST-120 is a product that removes PBUTs and is approved in Asia to slow CKD progression

Other Toxins

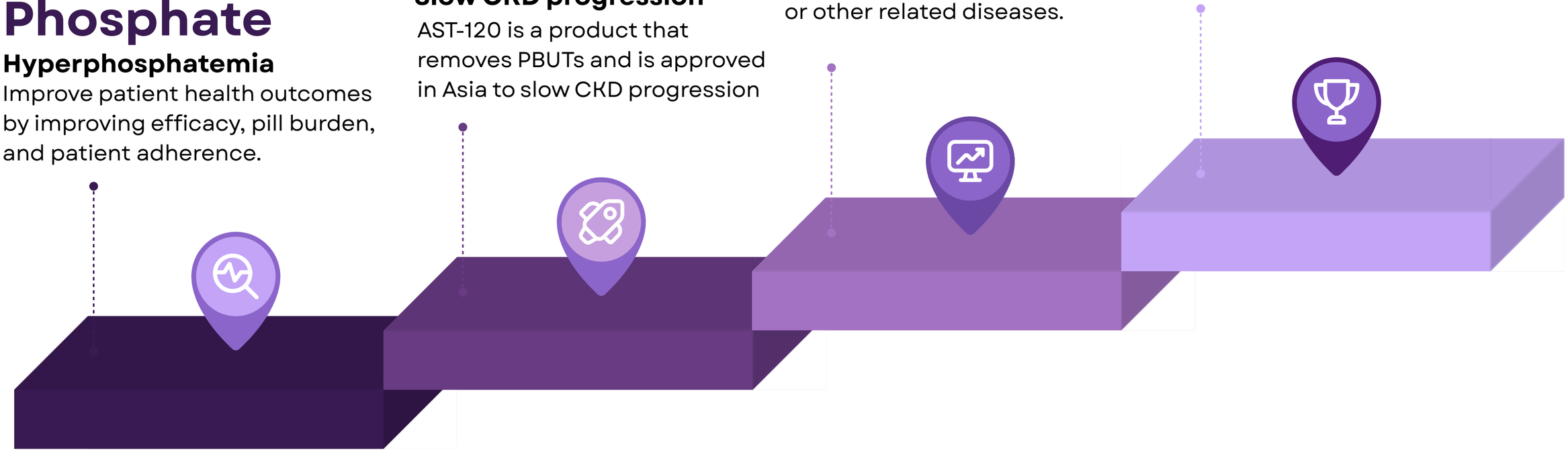
Target other diseases

Develop solutions for hepatic encephalopathy, hypernatremia, or other related diseases.

Dialysis

Disrupt a $100B+ market

Reduce dialysis runs or session time to reduce costs.



Team



Mari Winkler

Serial Entrepeur
Professor of Engineering



Pei-Hsin Wang

PhD Student



Clarke Chung

PhD Student



Paige DeOra

Clinical Research Coordinator
Bio-engineer



Nicolas Picon

MBA Candidate
Biotech Operator

COLLEGE OF ENGINEERING
UNIVERSITY of WASHINGTON

RAINIER CLINICAL RESEARCH CENTER

DEPARTMENT OF BIOENGINEERING
UNIVERSITY of WASHINGTON
College of Engineering & UW Medicine

FOSTER SCHOOL OF BUSINESS
UNIVERSITY of WASHINGTON

Empire Bio Diagnostics

Advisory Board



Jonathan Himmelfarb

Icahn School of Medicine at Mount Sinai

Nephrologist and Clinical Trial Expert



Wendy Garrett

HARVARD T.H. CHAN SCHOOL OF PUBLIC HEALTH

Pre-clinical Model Expert and Physician



Glenda V. Roberts

Icahn School of Medicine at Mount Sinai

Patient Advocate

Mentors



Amicia Elliott
VP at Form Bio

Startup entrepreneur



Neil McDonnell
CEO at Seal Rock Therapeutics

Former Deputy Director of Strategy, Global Health Program at the Gates Foundation
Serial entrepreneur



Ivan Liachko
CEO at Phase Genomics

Startup entrepreneur



Jonathan Heller
Biotech Leader

Drug Development Expert

Traction

Research Grants

$3.5M

CENTER FOR DIALYSIS INNOVATION
Northwest Kidney Centers | UW Medicine

NIH
National Institutes of Health

ISAC
INNOVATIVE SCIENCE ACCELERATOR PROGRAM

Mount Baker Foundation

1 US Patent Awarded

2 Provisional Patents

US Patent 12,263,193
PCT/US2024/034373,
63/572619

Training

NSF CORPS
NSF Innovation Corps

Nucleate

W COMOTION INNOVATION GAP FUND

EQUALIZE STARTUPS

KIDNEY RESEARCH INSTITUTE

Pre-clinical Progress

Small animal studies

30+ Customer Discovery Interviews

Collaborators

UNIVERSITY of WASHINGTON

HARVARD

MAYO CLINIC

Icahn School of Medicine at Mount Sinai

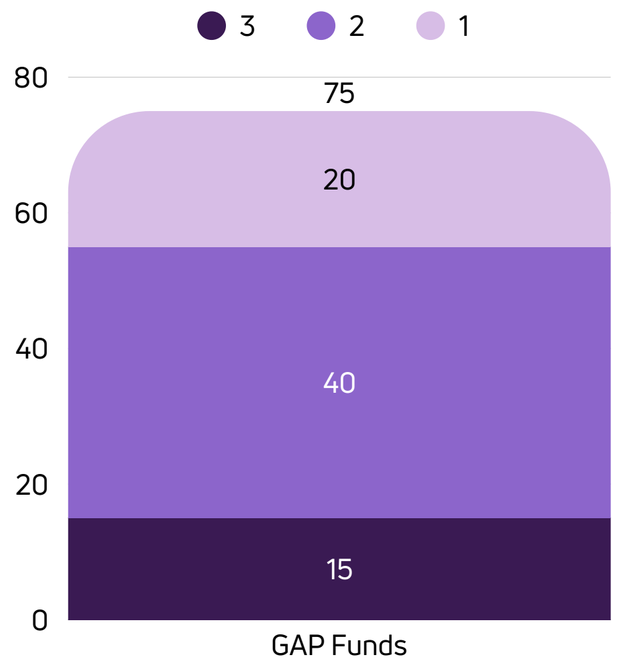
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UT THE UNIVERSITY OF TOLEDO 1872

What $75K Unlocks for THERA

It will fund 8 months of commercial work to achieve these milestones:

- ✓ **1) Market and Clinical Validation**: Conduct 40-60 structured interviews with kidney space stakeholders to solidify the clinical need.
- ✓ **2) Regulatory, Clinical, and Manufacturing Strategy**:
  - Hire an FDA-experienced regulatory consultant to choose the best regulatory strategy.
  - Work with clinical partners to plan the structure of the clinical trials.
  - Define the toxicology strategy and required preclinical safety studies.
  - Identify 3–5 CDMOs with GMP hydrogel manufacturing experience.
- ✓ **3) Investor materials and funding roadmap**:
  - Create a seed round budget plan with milestones that will unlock the next round of funds
  - Build a targeted investor list by thesis fit
  - Create an investor pitch deck, 2-page summary, and 18-month financial model
- ✓ **Spin-Out company**





Thank you!

Join us in revolutionizing CKD treatment with TheraT!

Questions?