



**UNICYCIVE**

THERAPEUTICS INC.

NASDAQ: UNCY

# Novel Treatments for Kidney Disease

Company Presentation

September 2024



# Forward Looking Statements

This presentation contains certain “forward-looking” statements that are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical or present facts, are forward-looking statements, including statements regarding our future financial condition, future revenues, projected costs, prospects, business strategy, and plans and objectives of management for future operations, including our plans for clinical trials and plans to submit for regulatory filings. In some cases, you can identify forward-looking statements by terminology such as “believe,” “will,” “may,” “might,” “estimate,” “continue,” “anticipate,” “intend,” “target,” “project,” “model,” “should,” “would,” “plan,” “expect,” “predict,” “could,” “seek,” “goal,” “potential,” or the negative of these terms or other similar terms or expressions that concern our expectations, strategy, plans, or intentions. These statements are based on our intentions, beliefs, projections, outlook, analyses, or current expectations using currently available information, and are not guarantees of future performance, and involve certain risks and uncertainties. Although we believe that the expectations reflected in these forward-looking statements are reasonable, we cannot assure you that our expectations will prove to be correct. Therefore, actual outcomes and results could materially differ from what is expressed, implied, or forecasted in these statements. Any differences could be caused by a number of factors including but not limited to: our expectations regarding the timing, costs, conduct, and outcome of our clinical trials, including statements regarding the timing of the initiation and availability of data from such trials; the timing and likelihood of regulatory filings and approvals for our product candidates; whether regulatory authorities determine that additional trials or data are necessary in order to obtain approval; our ability to obtain funding for our operations, including funding necessary to complete further development and commercialization of our product candidates; our plans to research, develop, and commercialize our product candidates; the commercialization of our product candidates, if approved; the rate and degree of market acceptance of our product candidates; our expectations regarding the potential market size and the size of the patient populations for our product candidates, if approved for commercial use, and the potential market opportunities for commercializing our product candidates; the success of competing therapies that are or may become available; our expectations regarding our ability to obtain and maintain intellectual property protection for our product candidates; the ability to license additional intellectual property relating to our product candidates and to comply with our existing license agreements; our ability to maintain and establish relationships with third parties, such as contract research organizations, suppliers, and distributors; our ability to maintain and establish collaborators with development, regulatory, and commercialization expertise; our ability to attract and retain key scientific or management personnel; our ability to grow our organization and increase the size of our facilities to meet our anticipated growth; the accuracy of our estimates regarding expenses, future revenue, capital requirements, and needs for additional financing; our expectations related to the use of our available cash; our ability to develop, acquire, and advance product candidates into, and successfully complete, clinical trials; the initiation, timing, progress, and results of future preclinical studies and developments and projections relating to our competitors and our industry.

Additional factors that could cause actual results to differ materially from our expectations can be found in our Securities and Exchange Commission filings. Moreover, we operate in a very competitive and rapidly changing environment. New risk factors emerge from time to time, and it is not possible for our management to predict all risk factors, nor can we assess the effects of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in, or implied by, any forward-looking statements. All forward-looking statements included in this presentation are expressly qualified in their entirety by these cautionary statements. The forward-looking statements speak only as of the date made and, other than as required by law, we undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise.

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# Investment Thesis

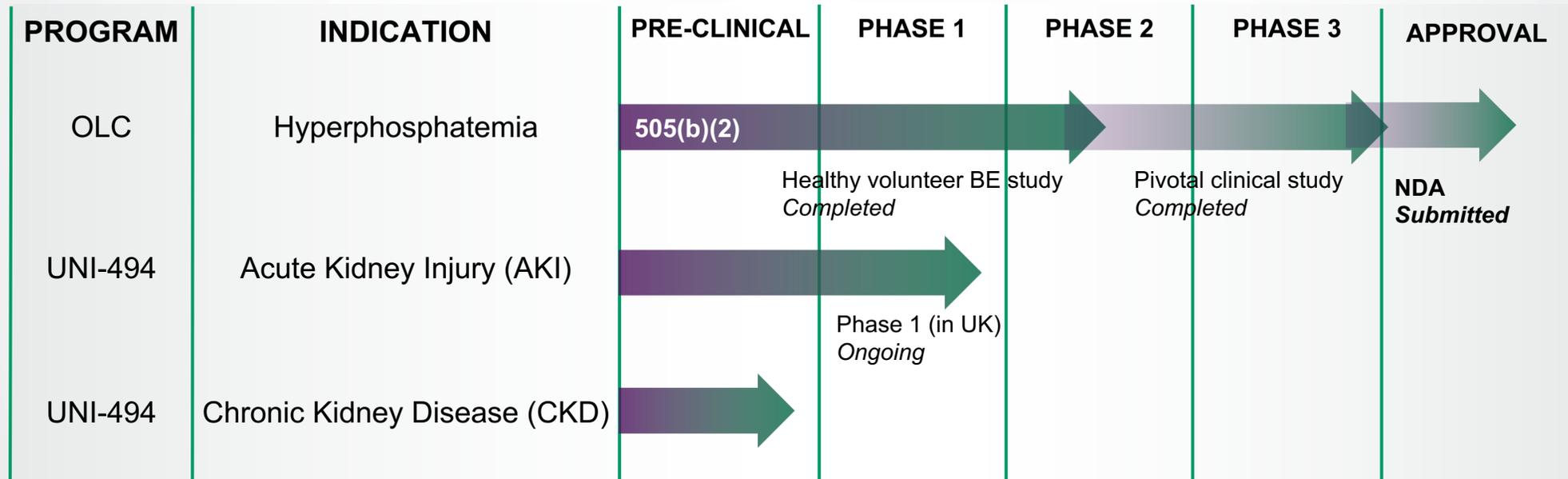


- New Drug Application (NDA) submission in August 2024 for lead program
  - Positive pivotal trial results announced in Q2 2024
  - Potential best-in-class product with de-risked path to approval and strong IP protection
- Near-term commercial opportunity in a multibillion-dollar, unsatisfied market with potential to improve treatment paradigm
- Seasoned management team with a winning track record in the market for 1<sup>st</sup> product
- Second pipeline program in clinical development for AKI with Orphan Drug Designation granted by the FDA

# Unicycive is Focused on Developing New Treatment Options for Kidney Diseases



## PIPELINE





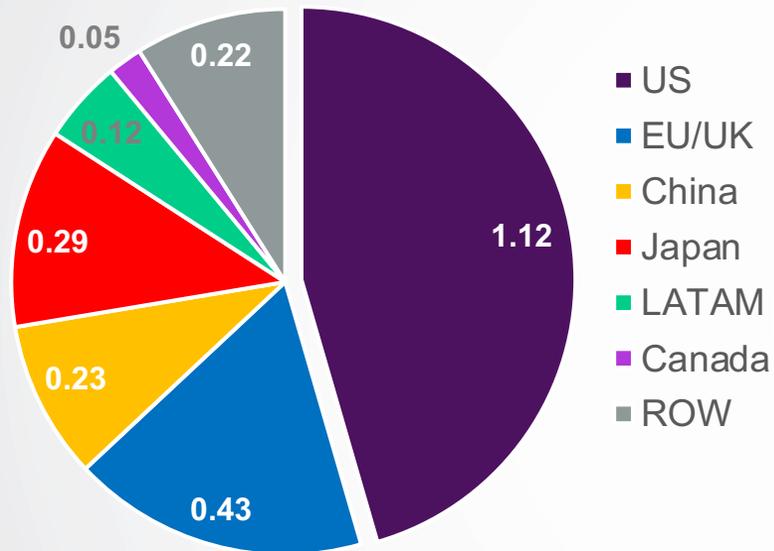
Lead Program:  
**Oxylanthanum Carbonate (OLC)**  
*For the Treatment of Hyperphosphatemia  
in Chronic Kidney Disease (CKD) Patients  
on Dialysis*

Oxylanthanum carbonate (OLC) is an unapproved investigational new drug being developed under FDA's 505(b)(2) regulatory pathway. If approved, OLC will share substantially the same product label and prescribing information as the reference-listed drug (RLD) Fosrenol (lanthanum carbonate) with the exception that OLC tablets are smaller in size and swallowed whole with water and not chewed.

# Hyperphosphatemia is a Large and Growing Market Opportunity

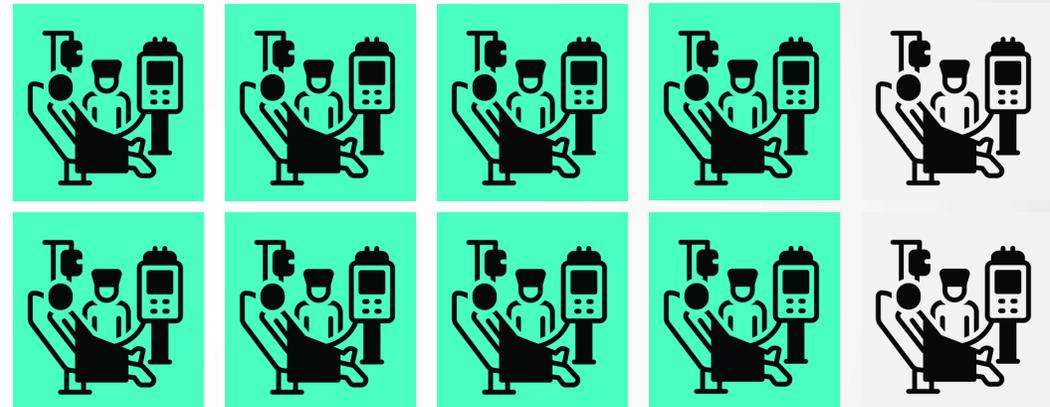


Worldwide Sales



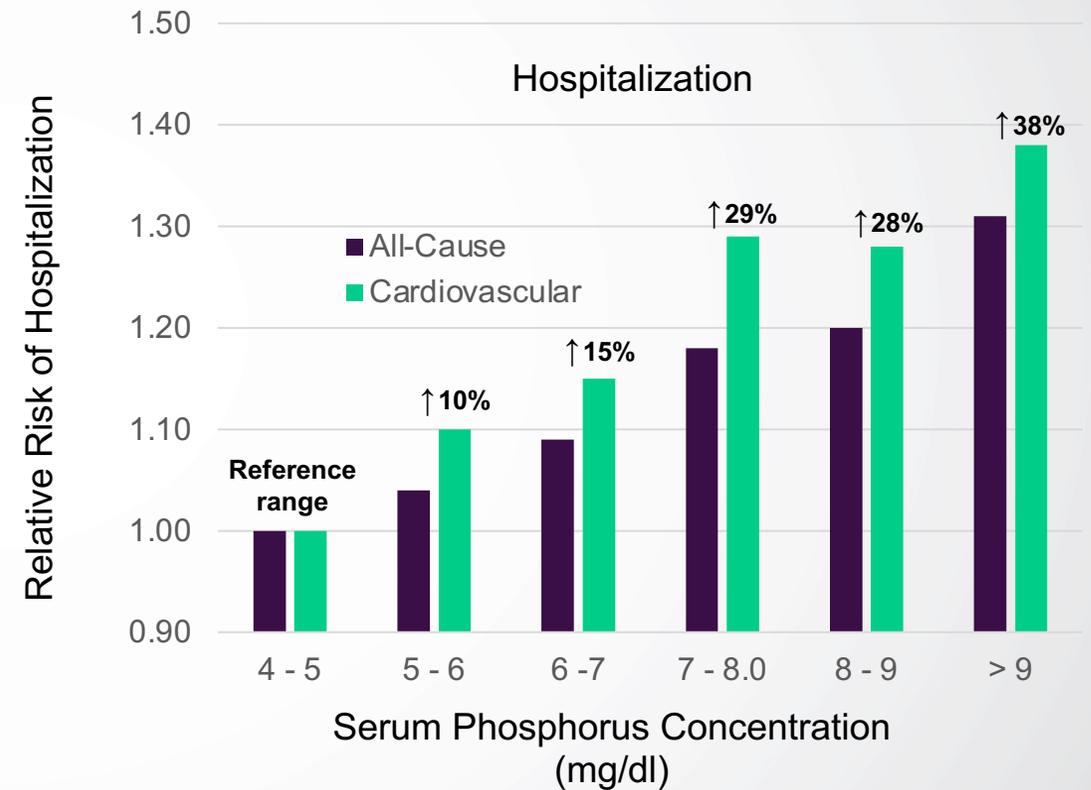
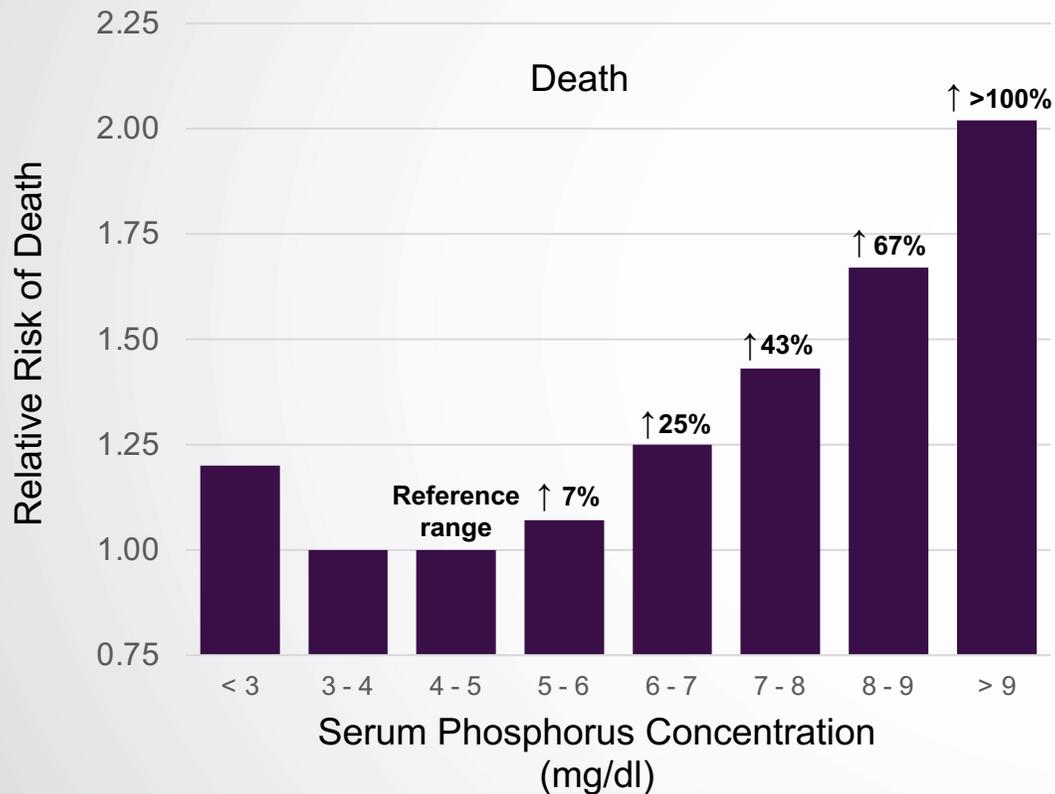
- \$2.5 Billion in 2021 (5.3% CAGR)
- US market over \$1billion
- Unicycive owns worldwide rights

## 8 out of 10 US Dialysis Patients Receive Phosphate Binders for Hyperphosphatemia

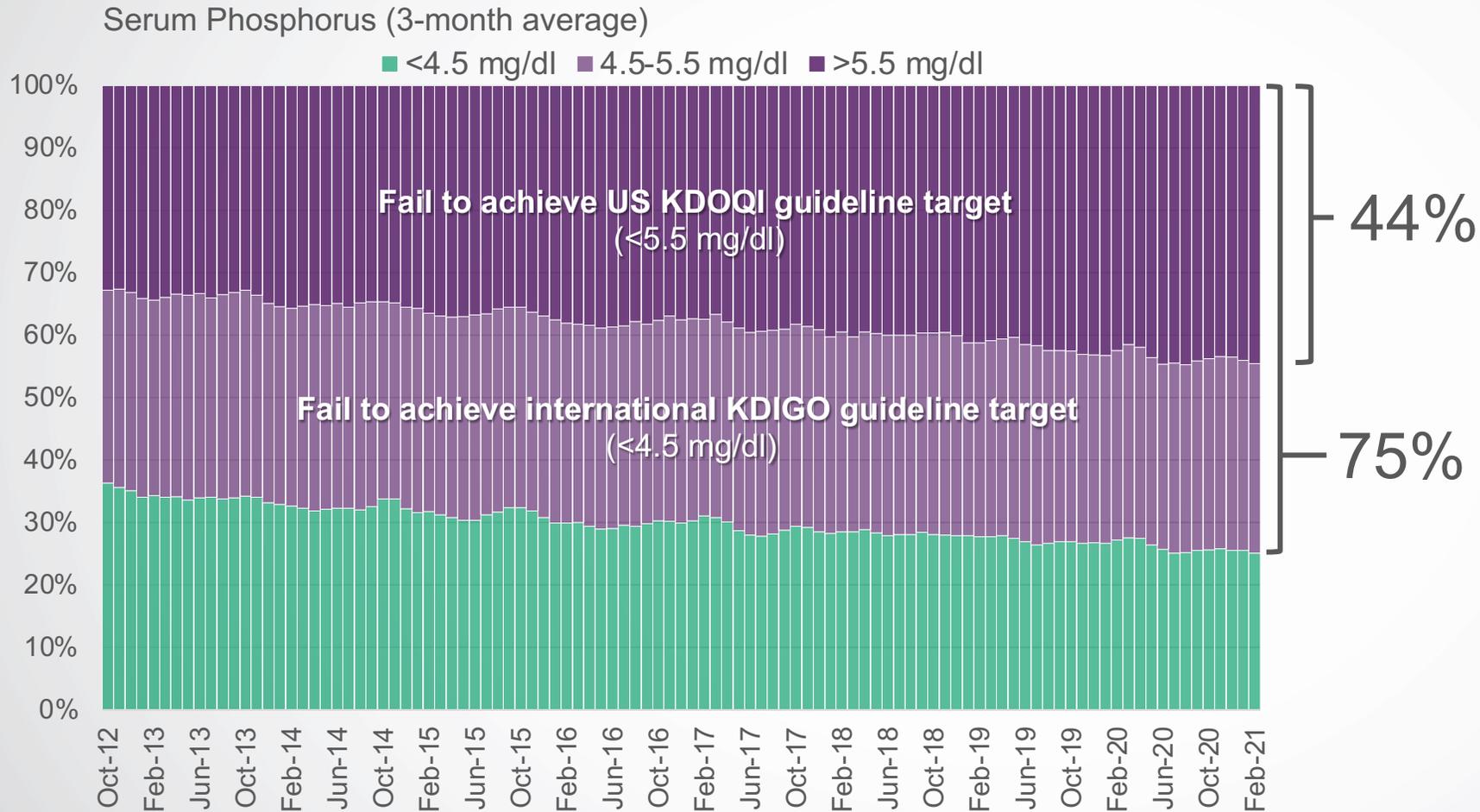


- >500,000 US dialysis patients in 2021 (3% growth rate)
- >400,000 (80%) receiving phosphate binders for hyperphosphatemia

# Uncontrolled Hyperphosphatemia is Strongly Associated with Increased Death and Hospitalization

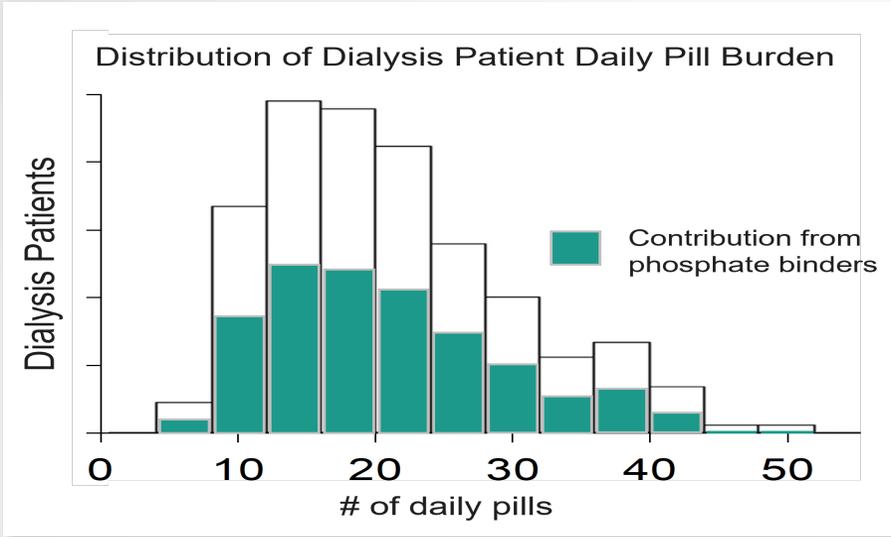


# The Unmet Need in Hyperphosphatemia



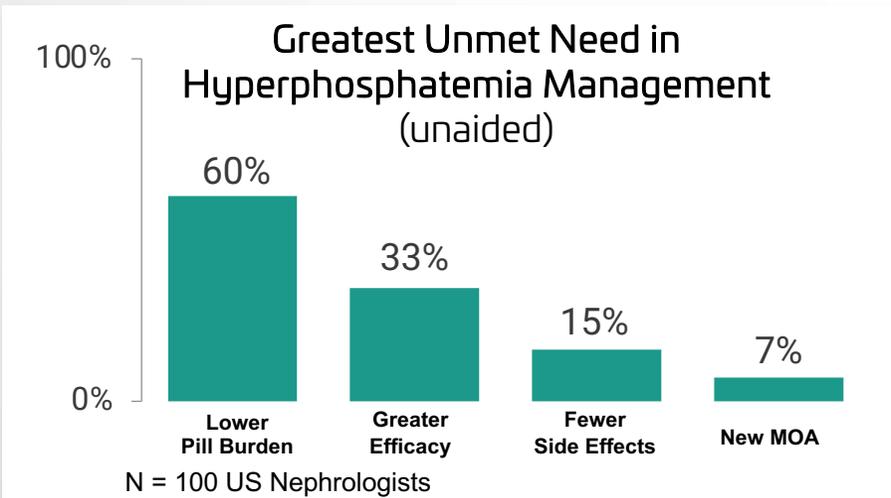
Despite the availability of 6 FDA-approved phosphate binders, a large percentage of patients fail to achieve serum phosphorus targets

# Addressing the Problem of Excessive Pill Burden



Daily pill burden for maintenance dialysis patients is among the highest across various chronic disease states including HIV/AIDS, diabetes mellitus, and congestive heart failure

- **19 pills per day** (median)
- **49%** of pill burden from phosphate binders
- Higher pill burden is independently associated with lower quality of life scores (HR-QOL)
- **62%** of patients are non-adherent (self-reported)
- Nephrologists report that lower pill burden is the greatest unmet need



*“Ideally, we would have phosphate binders with high phosphate-binding capacity (translating into low pill burden and good patient adherence)...**we still do not have such a phosphate binder.**”*

*Juergen Floege, MD, Nephrologist, Executive Committee Member, KDIGO CKD-MBD Guidelines*

# Oxylanthanum Carbonate (OLC) Product Profile



## Overview

- Potential **best-in-class product** being developed under **FDA's 505(b)(2) regulatory pathway** for the treatment of hyperphosphatemia
- OLC advantages:
  - (1) **Potency**: shares high phosphate binding capacity of lanthanum
  - (2) **Pill Burden**: smaller and fewer pills
  - (3) **Palatability**: swallowed whole with water and not chewed

## Proprietary Nanoparticle Technology

- UNICYCIVE has harnessed the phosphate binding potency of lanthanum to reduce the number and size of pills that patients must take to control hyperphosphatemia
    - Enhanced surface area
    - Lower molecular weight
    - Immediate release tablets
- 
- Enables smaller pills
  - Pills are swallowed (not chewed)

## Strong Global Intellectual Property



# Recommended Daily Starting Dose for Phosphate Binders

**MOST PRESCRIBED**

**Renvela<sup>®</sup>**

sevelamer carbonate 800 mg



2 tablets 3 times per day, swallowed  
Volume: 6.5 cm<sup>3</sup>

**Oxylanthanum Carbonate (OLC)\***

500 mg



1 tablet 3 times per day, swallowed  
Volume: 1.15 cm<sup>3</sup>

**Phoslo<sup>®</sup>**

calcium acetate 667 mg



2 tablets 3 times per day, swallowed  
Volume: 6.8 cm<sup>3</sup>

**Auryxia<sup>®</sup>**

ferric citrate 210 mg



2 tablets 3 times per day, swallowed  
Volume: 5.5 cm<sup>3</sup>

**Fosrenol<sup>®</sup>**

lanthanum carbonate 500 mg



1 tablet 3 times per day, chewed  
Volume: 4.0 cm<sup>3</sup>

**Velphoro<sup>®</sup>**

sucroferic oxyhydroxide 500 mg



1 tablet three times per day, chewed  
Volume: 5.5 cm<sup>3</sup>

\* Expected OLC recommended daily starting dose, if approved

Source: FDA approved package inserts, Pill volumes: Data on file, Unicycive Therapeutics, Product images are proportionally sized. Renvela<sup>®</sup> is a registered trademark of Sanofi., Auryxia<sup>®</sup> is a registered trademark of Akebia Therapeutics. Fosrenol<sup>®</sup> is a trademark of Takeda Pharmaceutical Company Limited, Phoslo<sup>®</sup> and Velphoro<sup>®</sup> are registered trademarks of Vifor Fresenius



# OLC Regulatory Strategy

505(b)(2) Requirement	Studies Conducted*
 <p>Demonstrate similar <b>Efficacy</b> to reference drug (Fosrenol)</p>	<p>Bridge to Efficacy</p> <p>Completed 12/2022</p> <p> <b>Bioequivalence Confirmed</b></p> <p><b>1</b> OLC vs Fosrenol® Pharmacodynamic Bioequivalence Trial in Healthy Volunteers</p>
 <p>Demonstrate similar <b>Safety / Tolerability</b> to reference drug (Fosrenol)</p>	<p>Bridge to Safety/Tolerability</p> <p>Completed 6/2023</p> <p> <b>Some quantitative variability observed – additional study needed</b></p> <p><b>2</b> OLC vs Fosrenol® Pre-Clinical Study</p> <p>Bridge to Safety/Tolerability</p> <p>Completed 6/2024</p> <p> <b>Favorable Tolerability Profile Confirmed</b></p> <p><b>3</b> Pivotal Clinical Tolerability/Exposure Trial in Dialysis Patients</p> <p><i>(A dashed orange arrow points from the 'Favorable Tolerability Profile Confirmed' box back to the 'Some quantitative variability observed' box.)</i></p>

\* All study designs agreed upon with FDA



# Safety & Tolerability of OLC in the Pivotal Study

Study objective to evaluate the safety & tolerability of clinically effective doses (serum phosphate  $\leq 5.5$  mg/dL) of OLC in CKD patients on dialysis

## Treatment-Related Adverse Events in $\geq 5\%$ Patients

Adverse Event	(N=86) n (%)
Diarrhea	8 (9%) <sup>a</sup>
Vomiting	5 (6%) <sup>a</sup>

a) Two patients experienced both diarrhea and vomiting

### Safety

- No treatment-related Serious Adverse Events (SAEs)
- 6 patients had non-treatment-related SAEs
- Most AEs were mild-to-moderate; only 2 patients with severe treatment-related AEs

### Tolerability

- Total discontinuation due to AEs was 6% (5/86)

**We believe that these results for OLC compare favorably to historical clinical experience with other phosphate lowering therapies and will support the demonstration of similarity to Fosrenol with regard to safety and tolerability required for our 505(b)(2) NDA filing**



# Adverse Event (AE) Profiles of Phosphate Lowering Therapies from FDA-Approved Product Labels

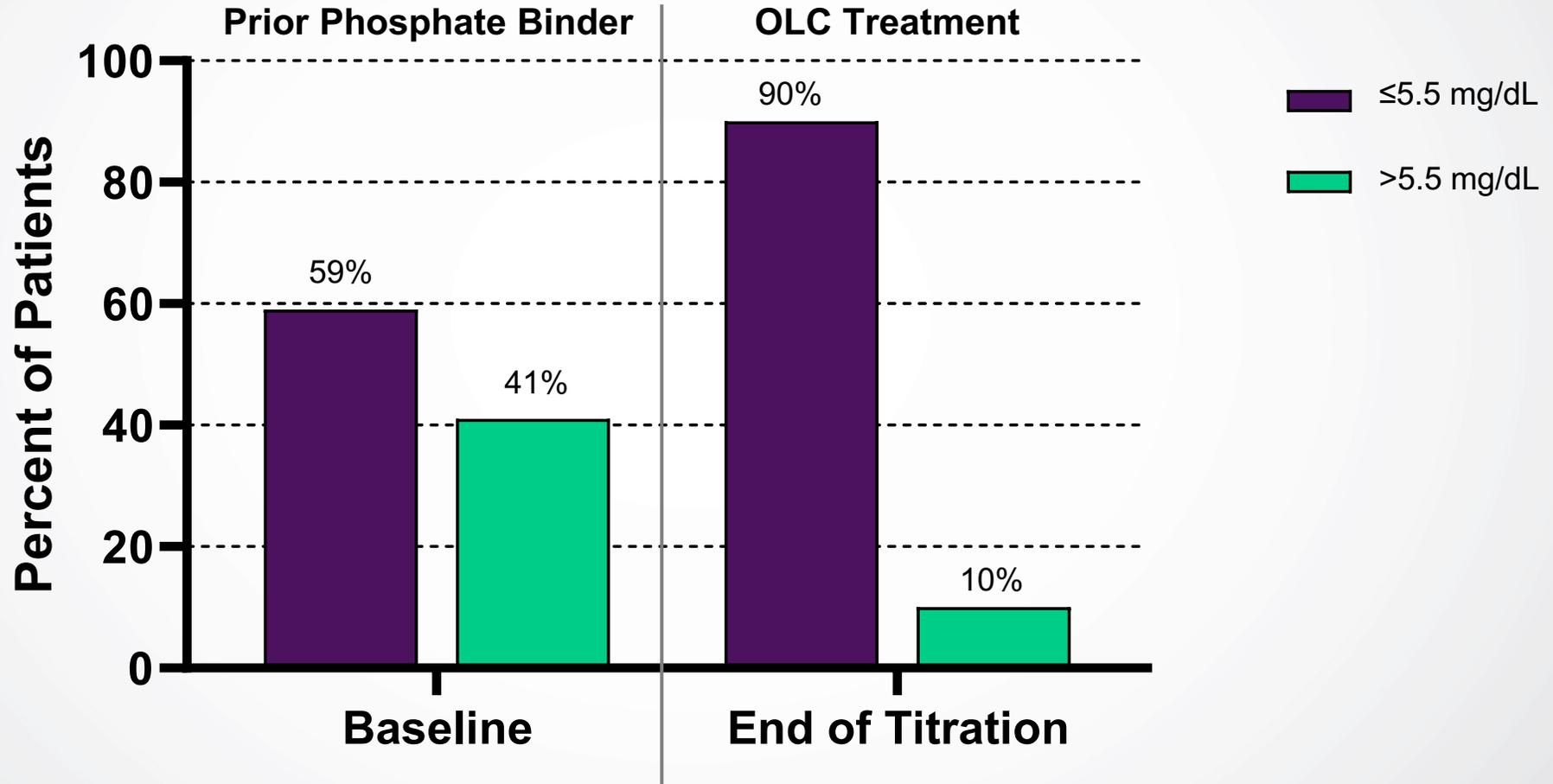
Fosrenol lanthanum carbonate		Renvela sevelamer carbonate		PhosLo calcium acetate		Velphoro sucroferric oxyhydroxide		Auryxia ferric citrate		Xphozah tenapanor	
Nausea	11%	Vomiting	22%	Hypercalcemia	13-16%	Diarrhea	24%	Diarrhea	21%	Diarrhea	43-53%
Vomiting	9%	Nausea	20%	Nausea	4-6%	Discolored feces	16%	Discolored feces	19%		
Abdominal pain	5%	Diarrhea	19%	Vomiting	2-4%	Nausea	10%	Nausea	11%		
		Dyspepsia	16%					Constipation	8%		
		Abdominal pain	9%					Vomiting	7%		
		Flatulence	8%					Cough	6%		
		Constipation	8%								

**Disclaimer:** FDA cautions that because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in clinical trials of a drug cannot to directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

**We believe that the AE profile observed in the OLC pivotal trial compares favorably with the historical clinical experience with Fosrenol and other phosphate binders and supports a similar safety profile required for our 505(b)(2) NDA filing**



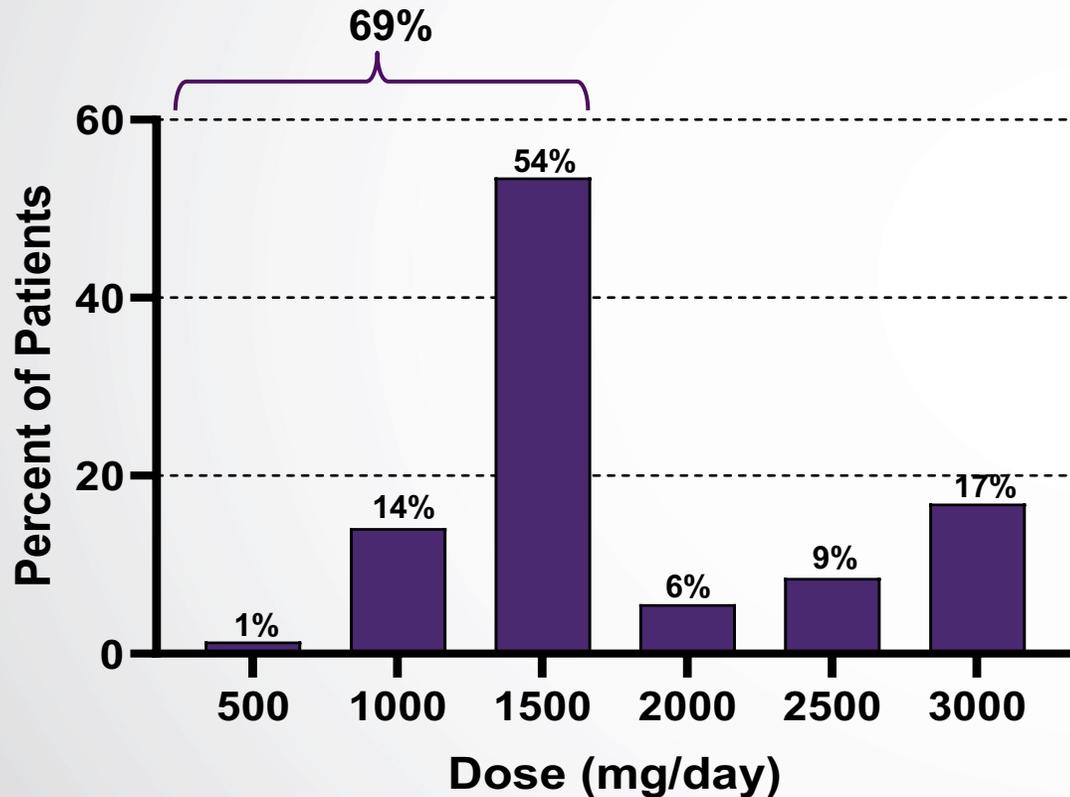
# Serum Phosphate Control in Safety Population (N=86)



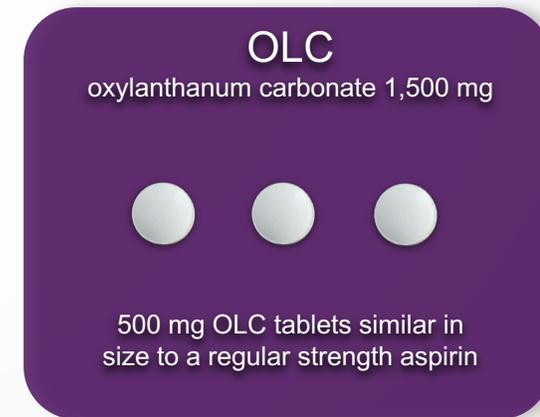
Baseline – Serum phosphate levels at screening before washout

End of Titration – includes last serum phosphate levels from all patients including those that discontinued during titration 77/86 (90%) / 9/86 (10%)

# Phosphate Control and Effective Dose in Evaluable Population (n=71)



**Of the 71 evaluable patients, 69% achieved a target serum phosphate level of  $\leq 5.5$  mg/dL at an OLC dose of  $\leq 1500$  mg/day or less**





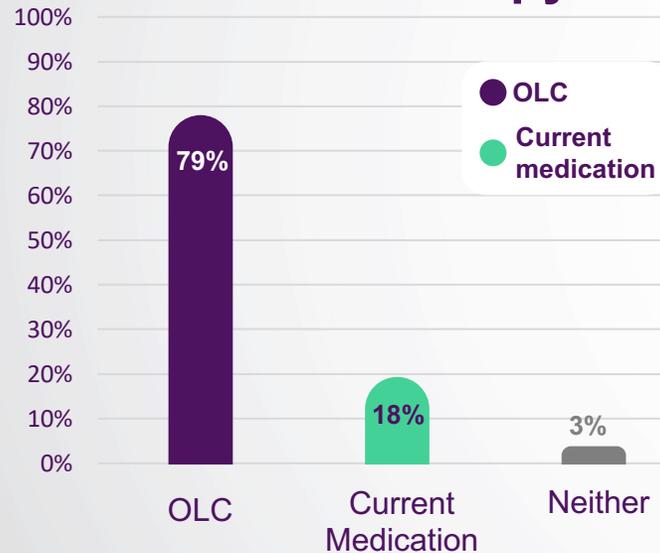
# OLC Patient Preference, Accessibility, and Satisfaction vs. Current Medication\*†

79% of patients preferred OLC over their current medication

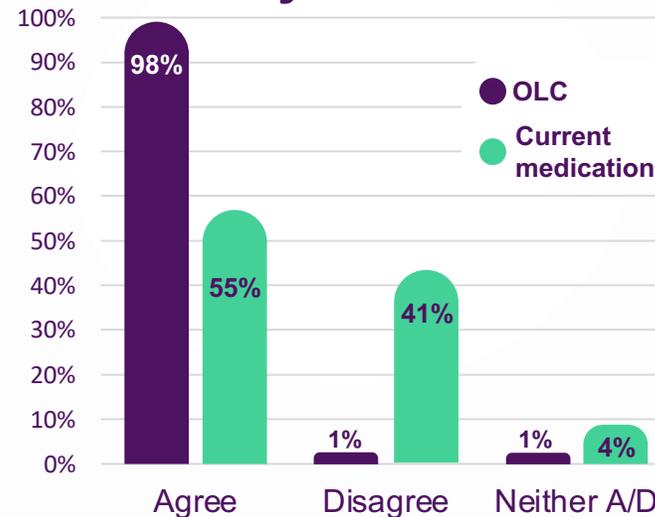
98% of patients said OLC was easy to take vs 55% with current medication

89% of patients were satisfied with OLC vs 49% with current medication

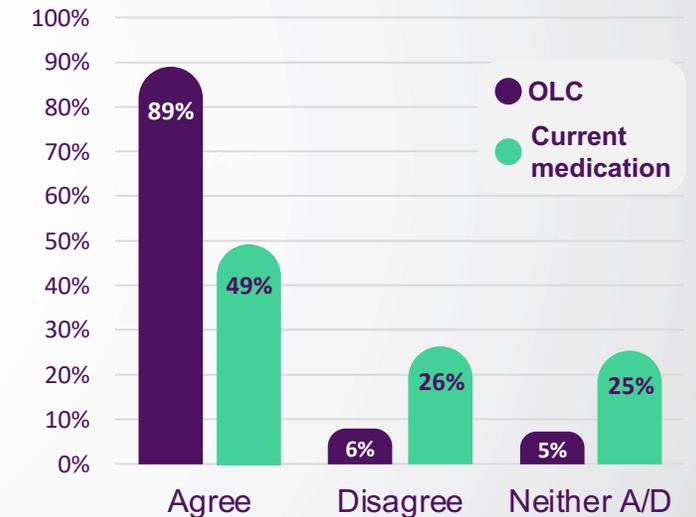
## Preferred Therapy



## Easy to Take



## Satisfaction



**Question:** Based on your experience in this clinical trial, do you prefer your current phosphate binder or OLC?

**Question:** Oxylanthanum carbonate is easy to take?  
**Question:** My current phosphate binder medication is easy to take?

**Question:** I am satisfied with oxylanthanum carbonate (OLC)?  
**Question:** I am satisfied with my current medication?

\*Current medication in the study population before OLC was 52% Renvela (sevelamer carbonate), 19% Phoslo (calcium acetate), 15% Aurxixa (ferric citrate), 13% Velphoro (sucroferric oxyhydroxide), and 1% Xphozah (tenapanor).

†These data are from a prespecified exploratory analysis of the UNI-OLC-201 Study.



# OLC Commercial Strategy

## Commercial planning underway to leverage potential large market opportunity

- Product positioning strategy and market shaping activities to support potential best-in-class value proposition
- Key Opinion Leader (KOL) engagement
- Distribution and channel strategy planning
- Deployment of purpose-built commercial model to maximize awareness, demand generation and market access for the launch of OLC
- Concentrated universe of phosphate binder prescribers allows for cost-efficient targeting with relatively small commercial footprint
- Expect to capitalize on CMS plan to expand patient access to phosphate binders in 2025
  - Minimum 2 years of separate Medicare Part B payment (Transitional Drug Add-On Payment Adjustment – TDAPA) for new drugs at 100% of average selling price (ASP)

# Oxylanthanum Carbonate (OLC) *IP Status*



## Strong Global Intellectual Property

- A family of patents (including composition of matter) were filed in 2011 for the U.S with exclusivity until 2031
- Corresponding patents granted in Canada, Europe, Japan, China, Australia, and other countries also have 2031 expiry
- Potential patent term extension through 2035



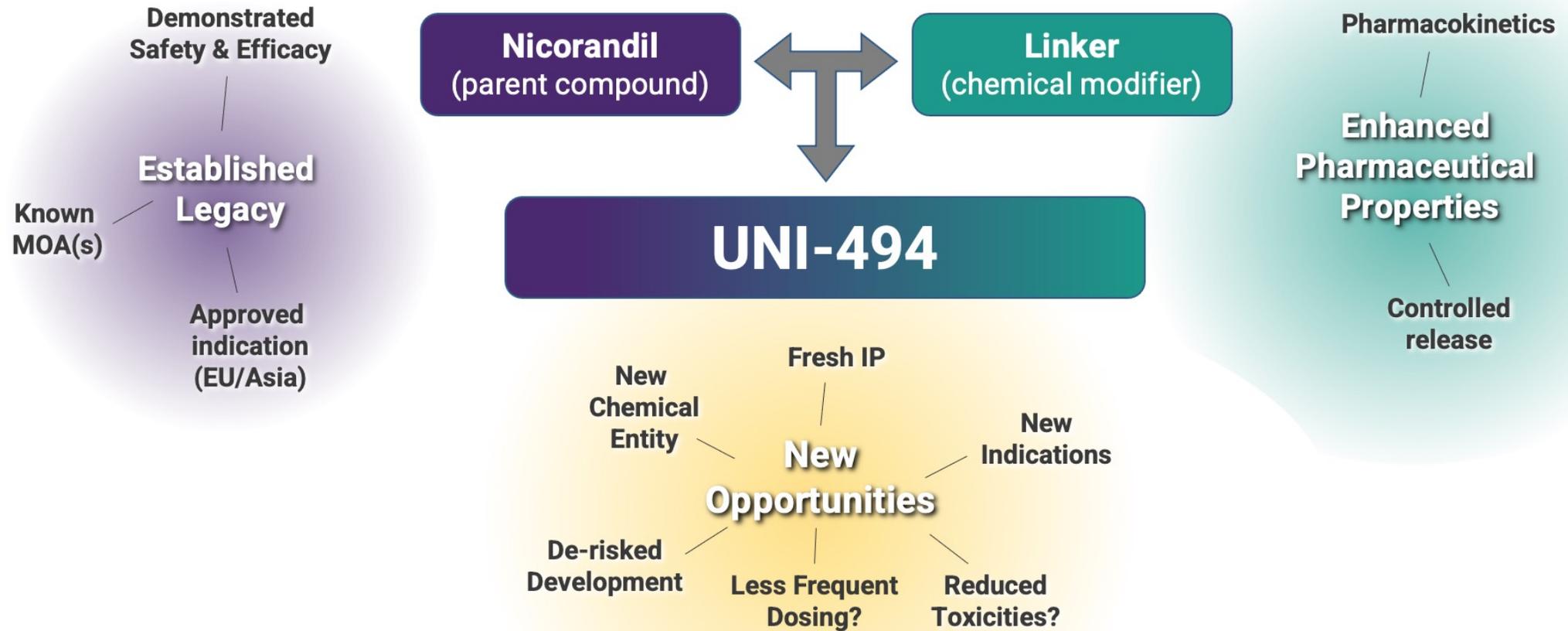
# **UNI-494: Mitochondrial-Targeted Therapy for Kidney Disease**



# UNI-494

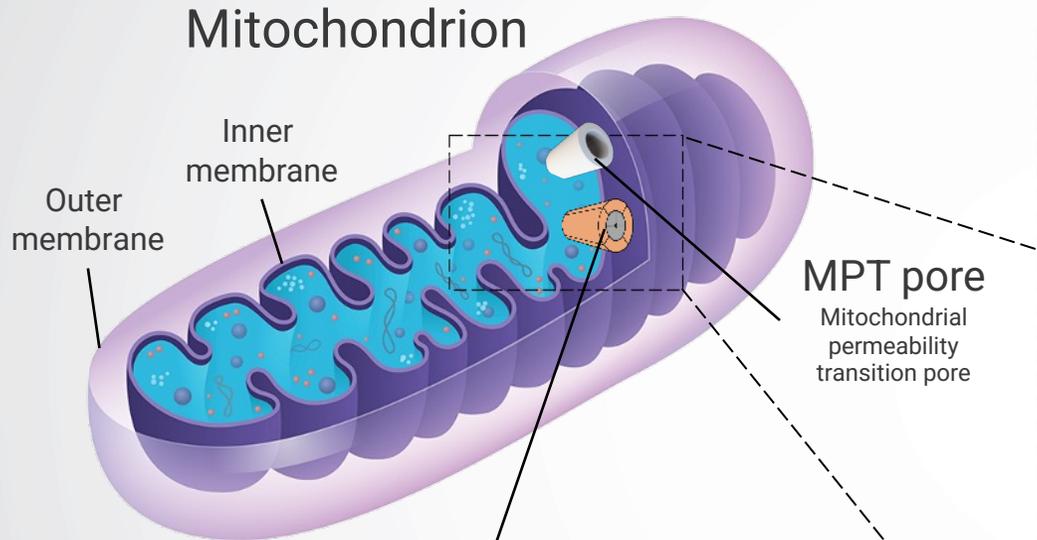
- Enrollment complete in Phase 1 dose-ranging study with results expected in Q3 2024
- Strong intellectual property protection with recent Method of Use patent valid to 2040
- Targeting Acute Kidney Injury (AKI)
  - Potential first indication in Delayed Graft Function
- U.S. Orphan drug designation for the prevention of Delayed Graft Function in kidney transplant patients
- Strong global intellectual property protection

# UNI-494 Profile

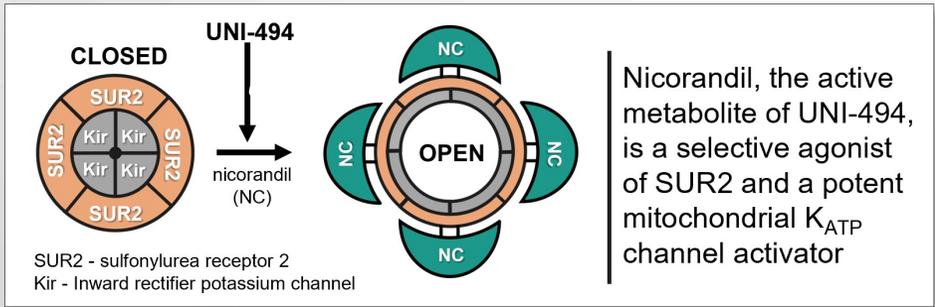
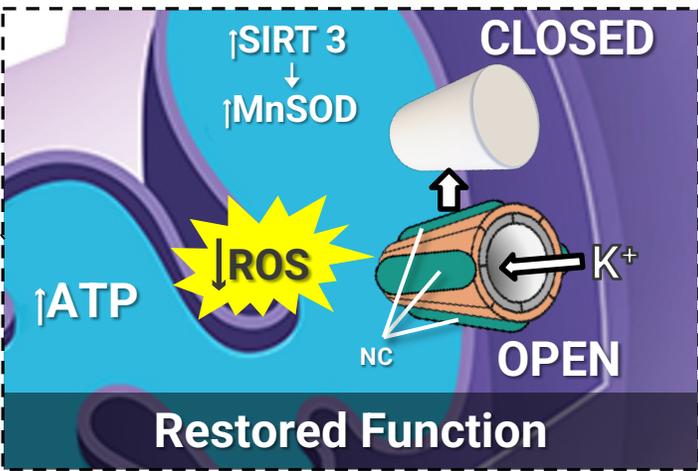


# UNI-494 Restores Mitochondrial Function

## Mechanism of Action



mitoK<sub>ATP</sub> channel



- A hallmark feature of mitochondrial dysfunction is chronic opening of MPT pores and overproduction of reactive oxygen species (ROS)
- Chronic opening of MPT pores leads to water and solute influx, swelling, injury and cell death

- UNI-494 is an ATP-sensitive K<sup>+</sup> channel (K<sub>ATP</sub>) activator
- Binds to SUR2 subunit of K<sub>ATP</sub> channel that in turn leads to closing of MPT pores
- Down-regulates production of ROS

Source: Hazel H Szeto *J Am Soc Nephrol* 28: 2865, 2017; Shiraishi et al., 2014

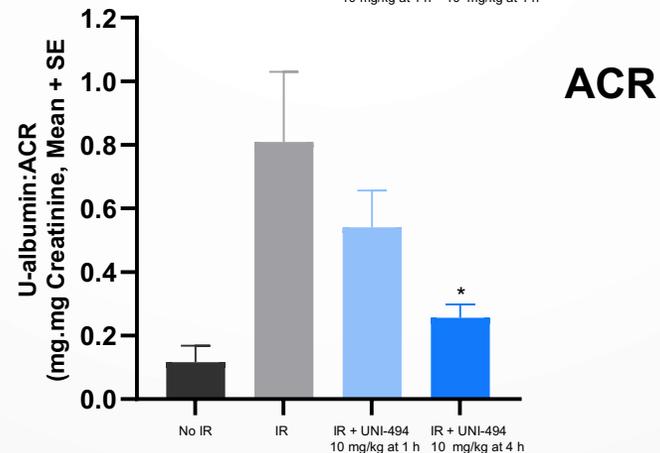
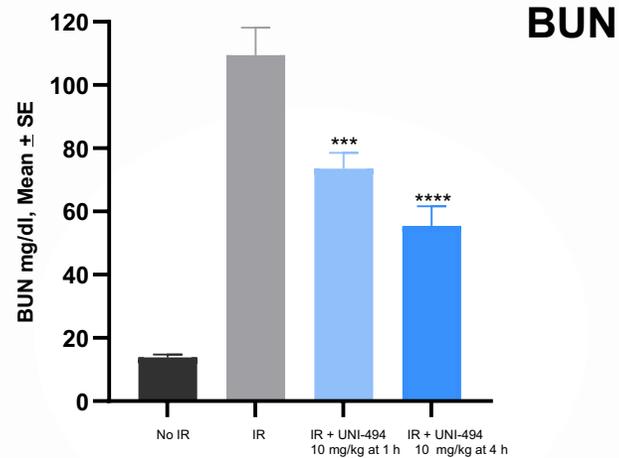
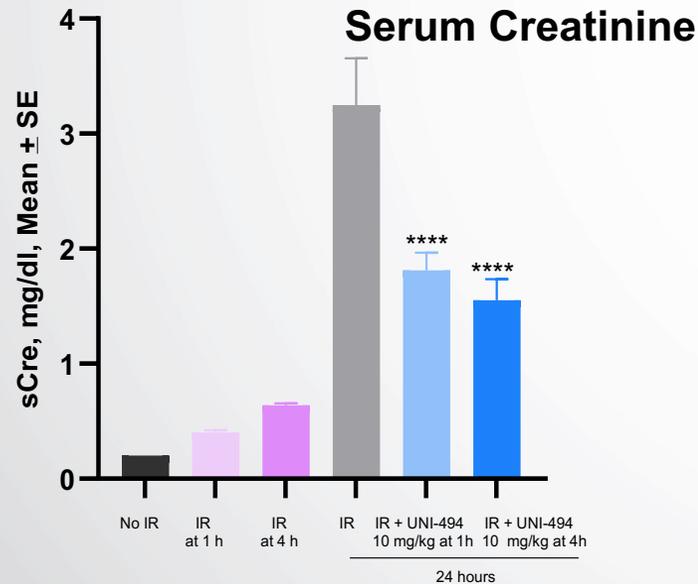
# Intravenous UNI-494 Ameliorates IRI in the Rat Kidney in a Therapeutic Mode



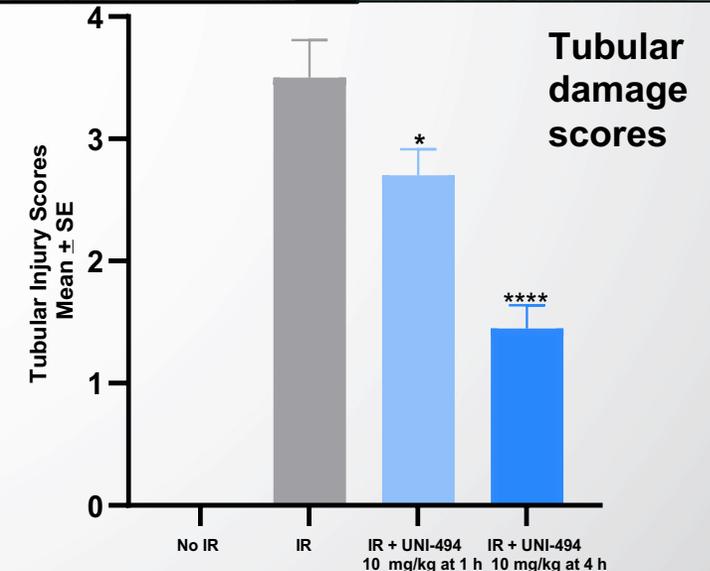
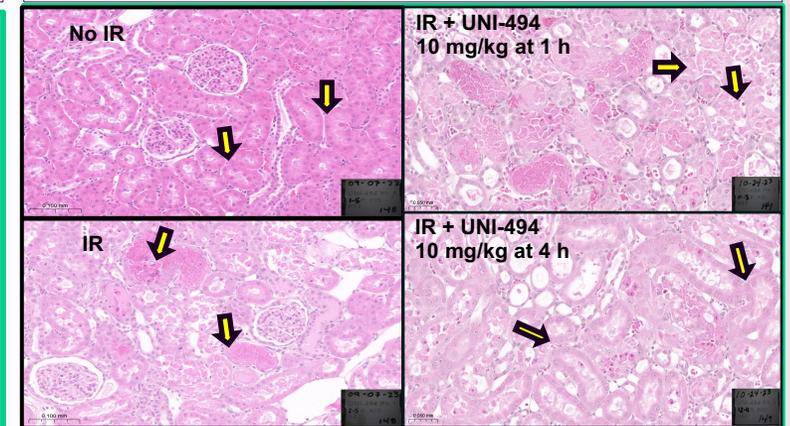
## Kidney Functional Markers

### Summary:

- Ischemia is 30 minutes
- UNI-494 dosed 1 or 4 hours after Ischemia
- Intravenous UNI-494 reduces sCr, BUN, ACR and tubule damage scores robustly
- Oral UNI-494 shown lesser degree of impact



## Tubular damage images and

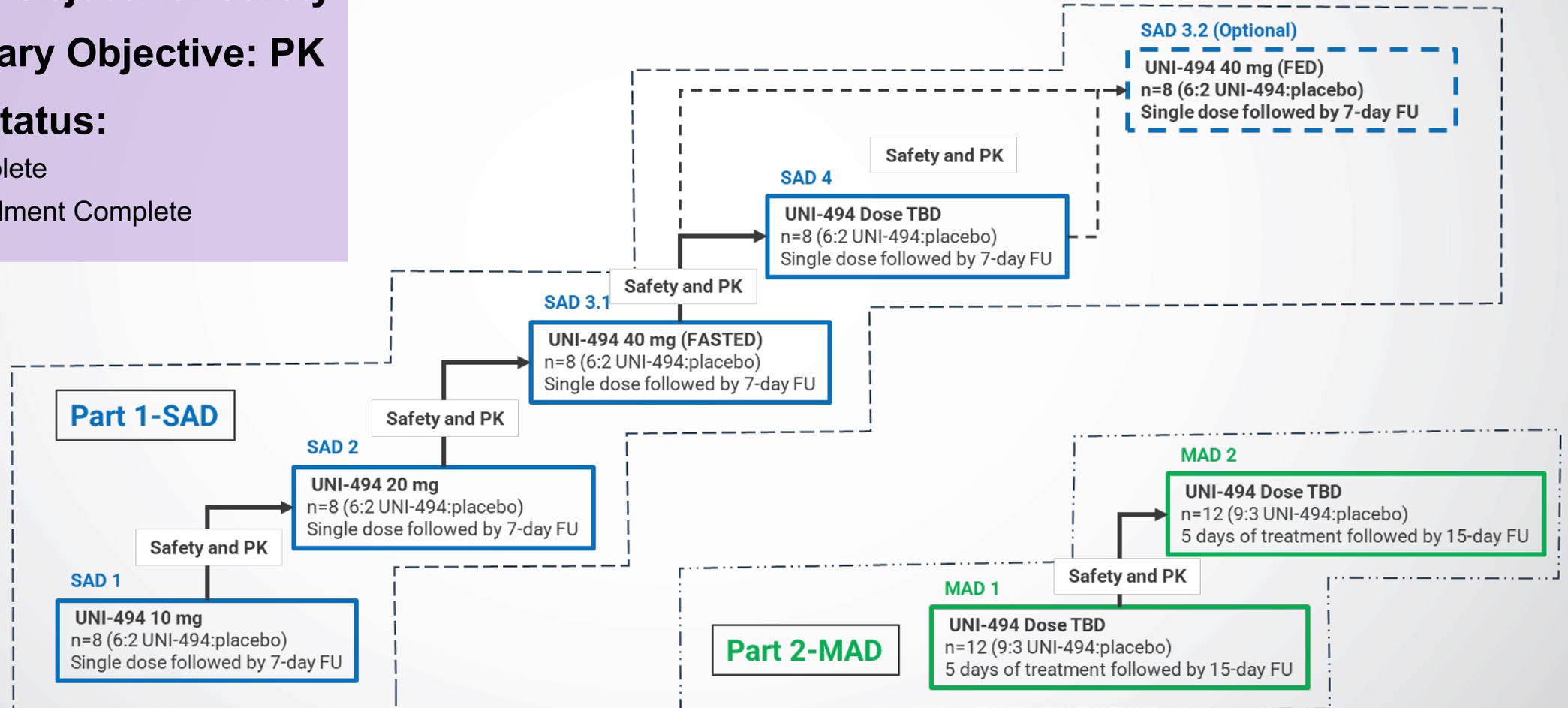


\*p = 0.05; \*\*\*p = 0.001; \*\*\*\*p = 0.0001 when compared to No IR group; Arrows pointed to proximal tubule; Tubular Scores as per Jablonski et al 1983



# UNI-494 Phase 1 Study Design & Status

- ✓ **Primary Objective: Safety**
- ✓ **Secondary Objective: PK**
- ✓ **Study Status:**
  - ✓ SAD Complete
  - ✓ MAD Enrollment Complete





# Corporate Overview

# Seasoned Management Team With Winning Track Record in Hyperphosphatemia Market



## Management



**Shalabh Gupta, MD**  
**Chief Executive Officer**  
NYU Medical Center,  
Genentech, UBS,  
Rodman & Renshaw



**John Townsend, CPA**  
**Chief Financial Officer**  
Guardion Health Sciences,  
Cytori Therapeutics



**Doug Jermasek, MBA**  
**EVP, Corporate Strategy**  
Genzyme-Sanofi, Akebia,  
Keryx, Pfizer, Abbott



**Pramod Gupta, PhD**  
**EVP, Pharmaceutical & Business Operations**  
Spectrum, B&L, Abbott



**Guru Reddy, PhD**  
**VP, Preclinical R&D**  
Spectrum, CIPHERGEN,  
Pangene, Yale

- Led Genzyme/Sanofi global renal business that grew Renvela (sevelamer) to a \$ billion+ franchise
- Led commercial team at Keryx that doubled Auryxia year/year revenues for 4 consecutive years
- Led preclinical/clinical and manufacturing development of oxylanthanum carbonate at Spectrum
- Responsible for the successful filing of multiple NDAs



# Unicycive Directors & Advisors

## Board of Directors



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Vivo Capital



**Sara Kenkare-Mitra, PhD**  
President & Head of R&D  
Alector



**Sandeep "Steve" Laumas, MD**  
Goldman Sachs,  
North Sound Capital



**Shalabh Gupta, MD**  
NYU Medical Center,  
Genentech, UBS,  
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Prof Emeritus of  
Medicine, UCSD



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subsidiary of Renal Associates



**Glenn Chertow, MD, MPH**  
Chief, Division of Nephrology at  
Stanford University School of  
Medicine



**Myles Wolf, MD**  
Chair of Medicine at Weill Cornell  
Medicine and Physician-in-Chief  
at New York Presbyterian/Weill  
Cornel Medical Center



# Financial Overview

Cash and Share Counts	
Cash and Cash Equivalents	\$41.8 million (as of June 30, 2024)
Market Cap	\$35.4 million (as of August 19, 2024)
Shares of Common Stock Outstanding	94.4 million common shares
Additional Preferred (if converted to common)	
Series A-2	26.2 million shares
Series B-2	7.9 million shares
Fully Diluted Shares (if preferred converted to common)	128.5 million shares
Fully Diluted Market Cap	\$48.2 million



# Expected Catalysts in 2024 and Beyond

## OLC for Hyperphosphatemia

- ✓ Successful bioequivalence study in healthy volunteers
- ✓ FDA alignment on regulatory path
- ✓ Completed enrollment in pivotal clinical trial
- ✓ NKF & ERA Presentations (Q2 '24)
- ✓ Pivotal trial readout (Q2 '24)
- ✓ NDA Submission (August '24)
- ❑ NDA Acceptance & PDUFA date
- ❑ Buildout of commercial infrastructure
- ❑ FDA Approval (mid-year '25)
- ❑ TDAPA Designation

## UNI-494 for Acute Kidney Injury

- ✓ Initiated Phase 1 clinical trial
- ✓ Orphan Drug Designation granted for the prevention of Delayed Graft Function in kidney transplant patients
- ✓ Oral and poster presentations at AKI and CRRT (Q1 '24)
- ✓ Oral presentations at ERA (Q2 '24)
- ✓ Method of Use patent granted by USPTO
- ✓ Phase 1 study enrollment complete (2024)
- ❑ Report Phase 1 study results (Q3 '24)
- ❑ Advance to Phase 2 POC Study (2024/2025)

# Investor Relations

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