UNICYCIVE
THERAPEUTICS INC.

COMPANY OVERVIEW

Unicycive Therapeutics is a biotechnology company developing novel treatments for kidney diseases. The company's lead investigational treatment is oxylanthanum carbonate (OLC), a phosphate-binding agent for the treatment of hyperphosphatemia in patients with chronic kidney disease who are on dialysis. OLC uses proprietary nanoparticle technology that is designed to reduce pill burden while maintaining therapeutic effectiveness.

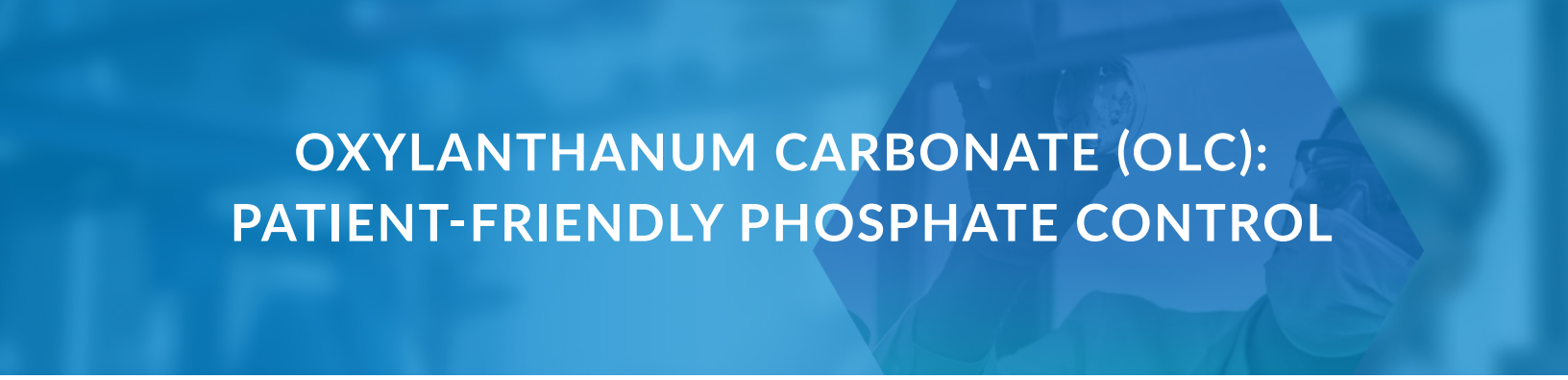
Unicycive's second investigational treatment, UNI-494, is being developed for conditions related to acute kidney injury (AKI). UNI-494 is a mitochondrial-targeted compound and has completed a Phase 1 dose-ranging safety study in healthy volunteers. The FDA has granted Orphan Drug Designation for the prevention of Delayed Graft Function (DGF) in kidney transplant patients.

The Company's development programs address areas of significant unmet medical need in renal care. With its focused pipeline and global intellectual property portfolio, Unicycive is advancing two differentiated treatment candidates with the potential to improve outcomes for patients with serious kidney diseases.

KEY CONSIDERATIONS

- **Focused Therapeutic Strategy:** Unicycive is developing two investigational treatments that target well-defined unmet needs in kidney disease, including hyperphosphatemia in dialysis patients and acute kidney injury.
- **Advanced Development Program for OLC:** Oxylanthanum carbonate is being developed under the FDA's 505(b)(2) regulatory pathway. The NDA was resubmitted in late December 2025 following a Type A meeting with the FDA to address a single deficiency identified in the prior Complete Response Letter. A new PDUFA date is expected in the first half of 2026, within 30 days of the NDA resubmission.
- **Progress in UNI-494 Development:** UNI-494 has completed a Phase 1 healthy volunteer study, and the company is working toward an IND filing to initiate a Phase 2 proof-of-concept study.
- **Intellectual Property Strength:** Unicycive holds issued U.S. and international patents for both OLC and UNI-494, together with pending applications that extend coverage across major global markets.
- **Cash Position and Runway:** As of September 30, 2025, Unicycive had $42.7 million in cash and cash equivalents, providing runway into 2027.
- **Partnership Expansion:** The company has executed strategic licensing agreements in Asia to support OLC commercialization and continues to evaluate additional partnership opportunities.

NASDAQ: UNCY



OXYLANTHANUM CARBONATE (OLC): PATIENT-FRIENDLY PHOSPHATE CONTROL

PROPRIETARY TECHNOLOGY

OLC uses a nanoparticle formulation designed to deliver more active drug in smaller tablets that can be swallowed whole.

REDUCED PILL BURDEN

Unicycive's formulation aims to lessen the daily pill load for dialysis patients who often struggle with existing phosphate binders.

STREAMLINED DEVELOPMENT

OLC advances through the FDA's 505(b)(2) pathway, which allows reliance on established safety and clinical data from lanthanum-based binders.

COMPLETE NDA SUBMISSION

The NDA, resubmitted in December 2025, is supported by three clinical studies, multiple preclinical studies, and chemistry, manufacturing and controls (CMC) data.

REGULATORY PROCESS

The NDA resubmission followed a Type A meeting with the FDA. A new PDUFA date is expected in the first half of 2026.

GLOBAL IP COVERAGE

Issued U.S. and international patents, along with pending applications, provide strong protection for OLC across major global markets.

ADVANCING TWO INVESTIGATIONAL TREATMENTS FOLLOWING OLC NDA RESUBMISSION

Unicycive Therapeutics is focused on developing treatments for serious kidney diseases where patients face limited therapeutic options. The company's lead investigational treatment, oxylanthanum carbonate (OLC), is being developed to improve phosphate control for chronic kidney disease patients on dialysis by reducing the pill burden associated with existing therapies.

OLC is progressing through the FDA's 505(b)(2) pathway, which allows Unicycive to leverage established safety and clinical data from lanthanum-based binders. The bioequivalence study comparing OLC with Fosrenol was completed in the fourth quarter of 2022, meeting all primary endpoints. The NDA for OLC was resubmitted in late December 2025 following a Type A meeting with the FDA, and a new PDUFA date is expected in the first half of 2026.

The company is also advancing UNI-494, a mitochondrial-targeted investigational treatment intended for conditions related to acute kidney injury. UNI-494 is a prodrug of nicorandil with improved properties and has completed a Phase 1 dose-ranging safety study in healthy volunteers. The FDA has granted Orphan Drug Designation for the prevention of Delayed Graft Function in kidney transplant patients.

Acute kidney injury has no FDA-approved drug treatments, and its severity often leads to dialysis or kidney transplant. By focusing on mitochondrial health, UNI-494 aims to address key biological pathways associated with kidney injury. Unicycive is preparing for further clinical development, including an IND filing to support a Phase 2 proof-of-concept study.

Across both programs, Unicycive's strategy is to target well-defined unmet needs in renal medicine. With issued U.S. and international patents, a strengthening financial position, and expanding partnership opportunities in Asia, the company is positioned to advance two differentiated investigational treatments that may improve outcomes for patients with advanced kidney diseases.

32 MILLION

People in the U.S. living with chronic kidney disease

>450,000

U.S. dialysis patients receiving phosphate binders

79%

Patients preferred OLC over prior phosphate binder therapy

>$1 BILLION

U.S. hyperphosphatemia treatment market

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UNICYCIVE THERAPEUTICS INC.

LEADERSHIP

Shalabh Gupta, MD
Founder, Chief Executive Officer, President, Chairman

- Founder of Unicycive and CEO since 2016.
- Background includes commercial strategy at Genentech and equity research roles at UBS and Rodman & Renshaw.
- Founder of multiple healthcare companies, including Biocycive and Globavir.
- Advisor to UCSF Innovation Center and Stanford Spark Program.
- Former attending physician and clinical faculty member at NYU School of Medicine.

John Townsend, CPA
Chief Financial Officer

- Over 25 years of financial leadership in biotechnology, medical devices, and high-tech manufacturing.
- Previously Vice President of Finance and Chief Accounting Officer for Unicycive.
- Held finance roles at Guardion Health Sciences and Cytori Therapeutics.
- Began his career at Deloitte; Certified Public Accountant in California.

Douglas Jermasek, MBA
Executive Vice President, Corporate Strategy

- More than 25 years of commercial leadership experience in biopharmaceuticals.
- Former Senior Vice President of Marketing and Strategy at Akebia Therapeutics and Keryx Biopharmaceuticals.
- Led Genzyme's Renal Global Business Unit, driving Renvela to more than $1 billion in global sales.
- Earlier roles at Intercept, Prometheus, Agouron Pharmaceuticals, and Abbott.

Guru Reddy, PhD
Vice President of Preclinical R&D

- More than 25 years of biopharmaceutical R&D experience, including 15 years at Spectrum Pharmaceuticals leading preclinical development and clinical pharmacology.
- Responsible for multiple NDA submissions and four FDA-approved drugs; holds 17 U.S. patents and has co-authored more than 30 publications.

Pramod Gupta, PhD
Executive Vice President, Pharmaceutical and Business Operations

- More than 25 years of global pharmaceutical leadership with roles at Spectrum Pharmaceuticals, Bausch & Lomb, Baxter, TAP Pharmaceuticals, and Abbott.
- Developed and commercialized over 40 pharmaceutical products worldwide; holds 12 U.S. patents and has published more than 50 scientific papers.