UNICYCIVE THERAPEUTICS INC.

Nasdaq: UNCY

Unicycive Therapeutics is a biopharmaceutical company focused on developing innovative treatments for kidney diseases. The lead drug, Oxylanthanum Carbonate (OLC), is an investigational phosphate-binding agent designed for treating hyperphosphatemia in patients with chronic kidney disease. UNI-494 is a novel new chemical entity targeting mitochondrial dysfunction, currently in development for treating acute kidney injury (AKI). These drug candidates reflect Unicycive's commitment to addressing significant unmet needs in renal health.

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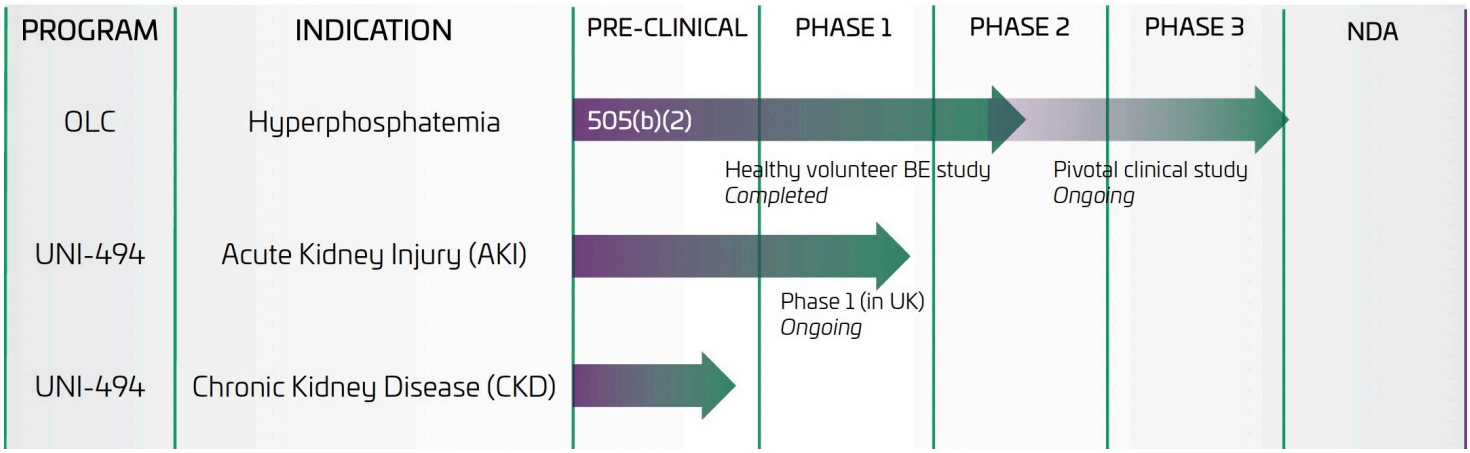
> INTERVIEW WITH EVP DOUG JERMASEK

Development Pipeline



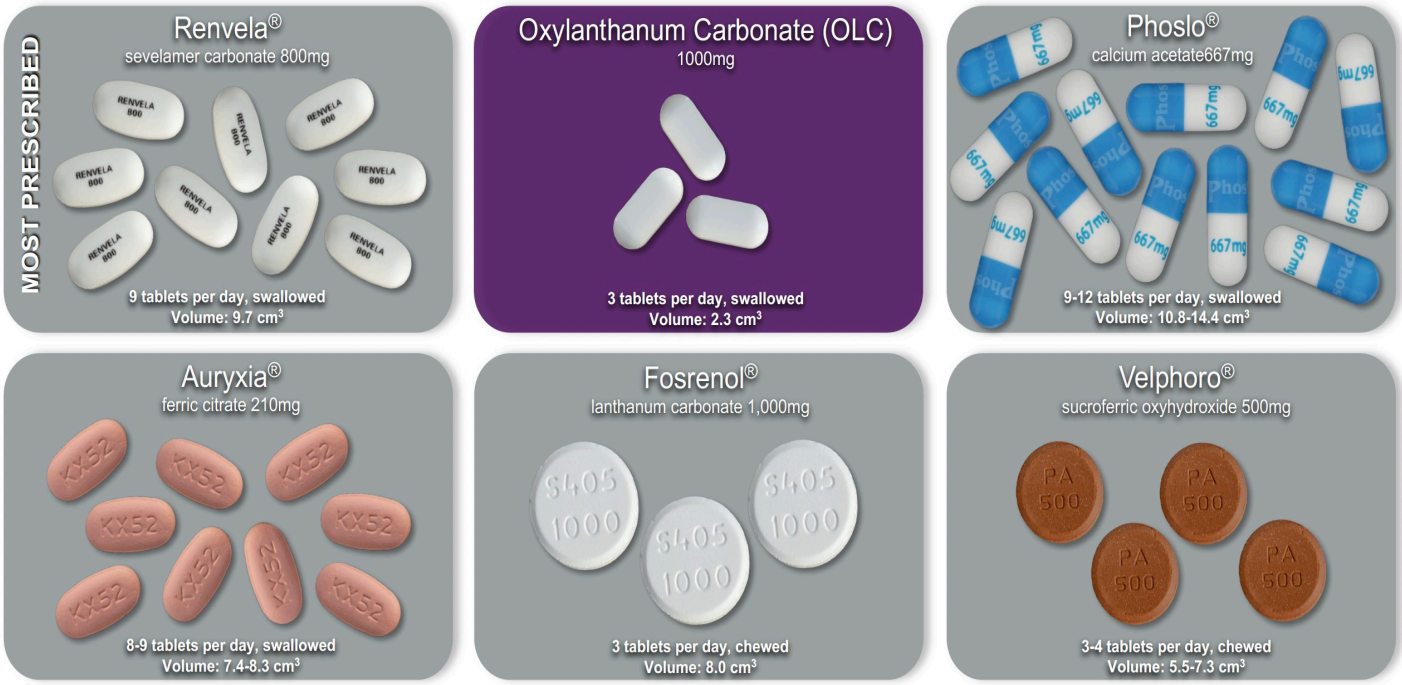
Addressing important patient needs in sizable markets within kidney disease

The kidneys perform vital functions, including releasing hormones, regulating blood pressure, maintaining fluid balance, and filtering waste products. Kidney diseases often result from chronic conditions like diabetes, coronary artery disease, and high blood pressure. These chronic conditions continue to increase in prevalence, leading to a growing number of kidney-related health issues. In the United States, approximately 32 million people have chronic kidney disease (CKD), with about half a million reaching Stage 5 CKD each year, which requires dialysis or a kidney transplant. This represents a significant unmet need for effective treatments.

Unicycive's key product, Oxylanthanum Carbonate (OLC), aims to address hyperphosphatemia in CKD patients. Hyperphosphatemia occurs when blood phosphate levels are above a certain threshold. It is common among patients with kidney disease, particularly those in late-stage CKD, as damaged or diseased kidneys lose their ability to effectively filter phosphate from the blood. While phosphate is necessary for building bones and teeth, producing energy, and constructing cell membranes, high levels can lead to bone and muscle problems, as well as an increased risk of heart attacks and strokes. Hyperphosphatemia affects at least 80% of patients with Stage 5 CKD who are on dialysis. Unicycive's focus on developing an innovative phosphate binder like OLC reflects its commitment to addressing this critical complication and providing relief to a large patient population in need of effective solutions.

Unicycive's Oxylanthanum Carbonate (OLC) Uses a Proven Mechanism of Action

Phosphate binders (PB) are commonly used to treat hyperphosphatemia, and the market for these treatments is substantial. In the United States alone, the market is valued at $1 billion, with a global value of approximately $2.5 billion. There are various types of phosphate binders, but they often have limitations, primarily due to the high pill burden, with patients having to take multiple large pills daily.



Source: Average daily dose: **dailymed.nlm.nih.gov**, Pill volumes: Data on file, Unicycive Therapeutics, Product images are proportionally sized | Renvela® is a registered trademark of Sanofi., Auryxia® is a registered trademark of Akebia Therapeutics. | Fosrenol™ is a trademark of Takeda Pharmaceutical Company Limited, Phoslo® and Velphoro® are registered trademarks of Vifor Fresenius

*Oxylanthanum Carbonate (OLC) is an unapproved investigational new drug developed under the FDA's 505(b)(2) regulatory procedure. If approved, OLC will share the same product label and prescribing information as the reference-listed drug Fosrenol (lanthanum carbonate), with the advantage of smaller tablets that are swallowed whole and not chewed..

Unicycive's investigational drug, Oxylanthanum Carbonate (OLC), aims to address this issue. OLC, developed with proprietary nanotechnology, is designed to significantly reduce the number and size of pills required, offering a more patient-friendly approach compared to current products on the market. OLC is a lanthanum-based phosphate binder, leveraging one of the most potent phosphate-lowering agents available.

If approved, OLC could offer a significant reduction in pill burden. Patients would take one smaller pill three times a day with meals, compared to other available options that require as many as 12 large pills per day. This advantage could lead to better patient compliance and improve overall quality of life for those with chronic kidney disease and hyperphosphatemia.

Hyperphosphatemia Market Opportunity

The phosphate binder (PB) market represents a significant opportunity, with revenue reaching about $2.5 billion globally in 2021, including over $1 billion in the U.S. market. Sevelamer holds about 50% of the market share, while calcium-based drugs account for 20%. The remaining 30% of the market is split among Fosrenol, Auryxia, and Velphoro. Oxylanthanum Carbonate (OLC) has patent exclusivity until 2031 in the U.S. and other global markets, providing a strong commercial runway.

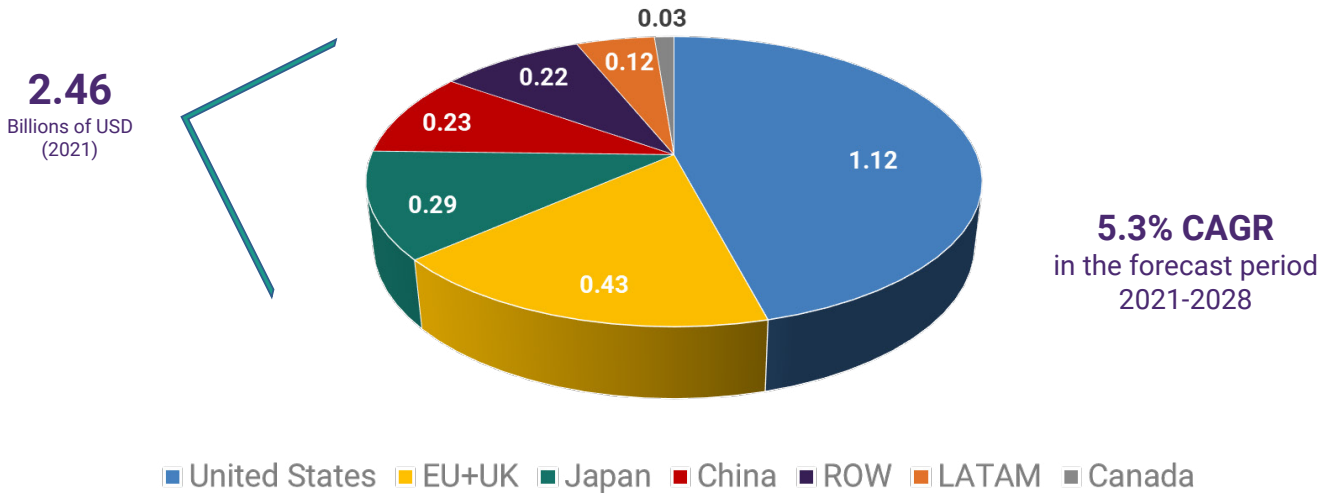
Oxylanthanum Carbonate (OLC) Global Intellectual Property

OLC is protected by a robust intellectual property portfolio, with patent coverage extending until 2031 in the U.S. and other regions. The comprehensive patent protection provides significant commercial advantages, allowing for a substantial period of exclusivity.

Note: Oxylanthanum Carbonate (OLC) is an unapproved investigational new drug being developed under the FDA's 505(b)(2) regulatory procedure. If approved, OLC will share the same product label and prescribing information as the reference-listed drug Fosrenol (lanthanum carbonate), with the advantage of smaller tablets that are swallowed whole and not chewed.

This strong intellectual property position and the proven market demand for phosphate binders position Unicycive to capitalize on a sizable market opportunity, offering a potentially superior product for managing hyperphosphatemia in chronic kidney disease patients on dialysis.

The diagram below summarizes the global market opportunity of Hyperphosphatemia



Unicycive owns worldwide rights to Oxylanthanum Carbonate (OLC)

Source: Fortune Business Insights™, *Hyperphosphatemia Treatment Market, 2021-2028*

Oxylanthanum Carbonate (OLC) is on a Significantly De-Risked Regulatory Pathway

Unicycive received a response from the FDA in Q4 2021 during a Type C meeting, providing a clear pathway for filing a New Drug Application (NDA) through the expedited 505(b)(2) pathway for U.S. approval. This pathway allows Unicycive to leverage pre-clinical and clinical data from the approved lanthanum-containing phosphate binder, Fosrenol, potentially reducing the need for extensive phase II and III clinical trials.

The company completed a bioequivalence (BE) study comparing phosphorus changes between Oxylanthanum Carbonate (OLC) and Fosrenol in healthy volunteers. Alongside this, a 6-month oral toxicity study in mice was also conducted, and data on manufacturability and commercial supply readiness for OLC were gathered. The BE study was completed in Q4 2022, with the data readout serving as a pivotal milestone in the regulatory process.

With these results, Unicycive is on track to file an NDA in mid-2024. Given a typical one-year review process, potential FDA approval could be expected in 2025, allowing Unicycive to commercialize Oxylanthanum Carbonate for treating hyperphosphatemia in patients with chronic kidney disease. This streamlined regulatory pathway and successful bioequivalence results position Unicycive well for the commercialization of OLC.

Go-to-market strategy and partnerships

In Q4 2022, Unicycive entered an agreement granting exclusive rights to develop, market, and commercialize Oxylanthanum Carbonate (OLC) to Lee's Pharmaceutical (HK) Limited for Mainland China, Hong Kong, and certain Asian markets. This partnership provides Unicycive with a strong local partner with deep domain expertise, expanding the opportunity for OLC in a significant market with a large patient base. As part of the agreement, Unicycive received an upfront fee of $1.0 million and is eligible for royalties on sales and additional milestone payments.

The strategic partnership with Lee's Pharmaceutical is expected to accelerate the commercialization of Oxylanthanum Carbonate in Asia, while Unicycive continues similar discussions with potential partners in other Asian regions and Europe to broaden its reach and ensure a successful go-to-market strategy.

UNI-494: Unicycive's Second Program for Acute Kidney Injury (AKI)

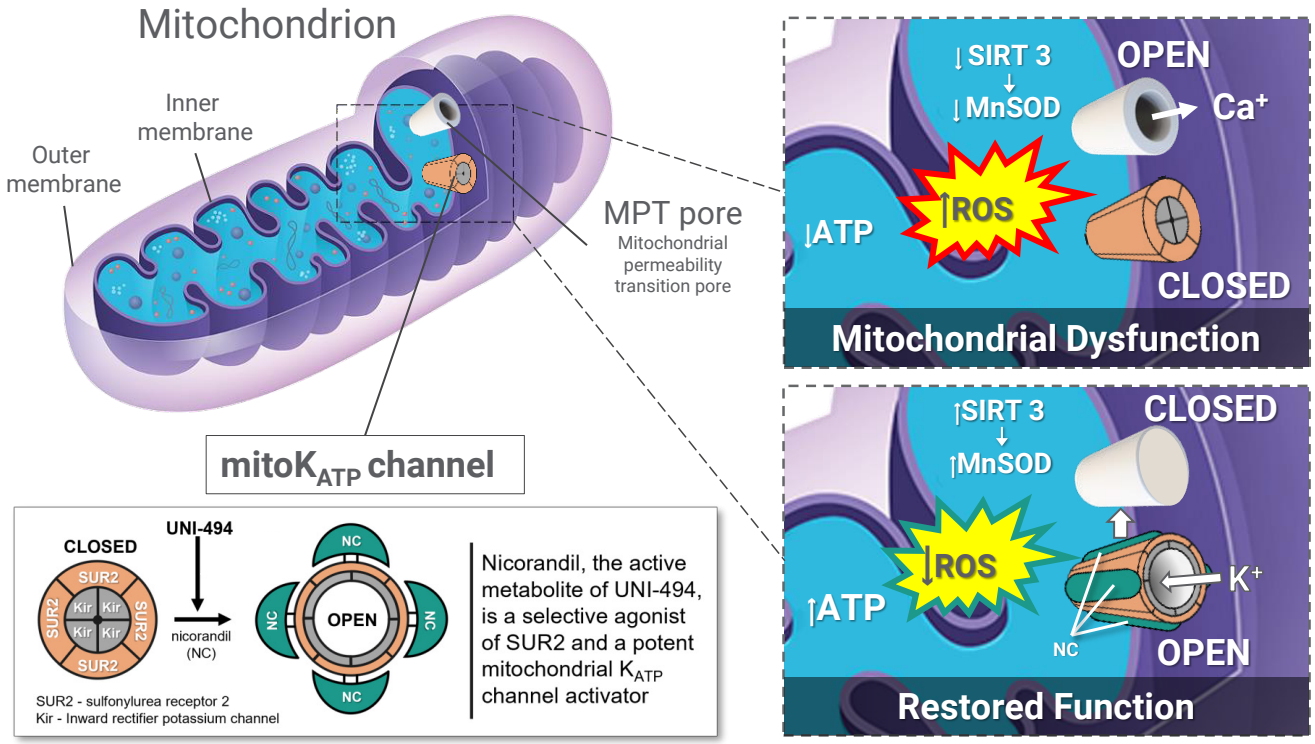
UNI-494 targets Acute Kidney Injury (AKI), a condition characterized by a sudden loss of kidney function, often leading to renal transplant or dialysis. AKI has a high mortality rate of about 24% in adults, and there are currently no FDA-approved drugs for this condition, indicating a significant unmet need.

UNI-494, a patent-protected pre-clinical drug candidate, aims to address AKI by targeting mitochondrial dysfunction, a key factor in AKI's pathophysiology. A Phase 1 clinical trial began in early 2023, marking an important step in its development. While UNI-494's initial focus is on treating AKI, Unicycive has plans to explore applications for chronic kidney diseases in the future.

How does UNI 494 work?

UNI-494 has a novel mechanism of action that focuses on mitochondria, the energy powerhouse of cells. Mitochondria play a crucial role in energy metabolism, and disruptions can lead to cell death and inflammation-related damage. Inflammation, which is a common factor in many chronic diseases, including kidney disease, can cause the opening of mitochondrial permeability transition (MPT) pores in the inner mitochondrial membrane, leading to mitochondrial swelling and cell death.

UNI-494 works by closing MPT pores, stabilizing and restoring mitochondrial function, thereby reducing cell damage and death. This unique action has potential applications in treating Acute Kidney Injury (AKI) and may also be useful in addressing other diseases linked to mitochondrial dysfunction.



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

UNI-494 has undergone various pre-clinical animal studies. Unicycive has initiated clinical development in the United Kingdom (UK) to expedite progress, filing a Clinical Trial Application (CTA) with the Medicines and Healthcare Products Regulatory Agency (MHRA) to begin a Phase 1 healthy volunteer study. This study received clearance in early 2023. Additionally, Unicycive plans to file an Investigational New Drug (IND) application with the FDA in 2024, with the intention of conducting further clinical trials in the United States.

FDA Regulatory Strategy for UNI-494

- Confirm that UNI-494 has acceptable tolerability in animal studies at desired doses.
- Identify does(s) for initial human study and demonstrate conversion of UNI-494 to its active metabolite (nicorandil) in animals.
- Seek regulatory clearance to initiate Phase I study.

Unique Attributes for Regulatory Approval of UNI-494

- Leverage pre-clinical and clinical data from nicorandil outside the U.S. with a comparability package.
- Design a Phase 2 clinical proof-of-concept trial in a more homogenous subset of AKI patients.

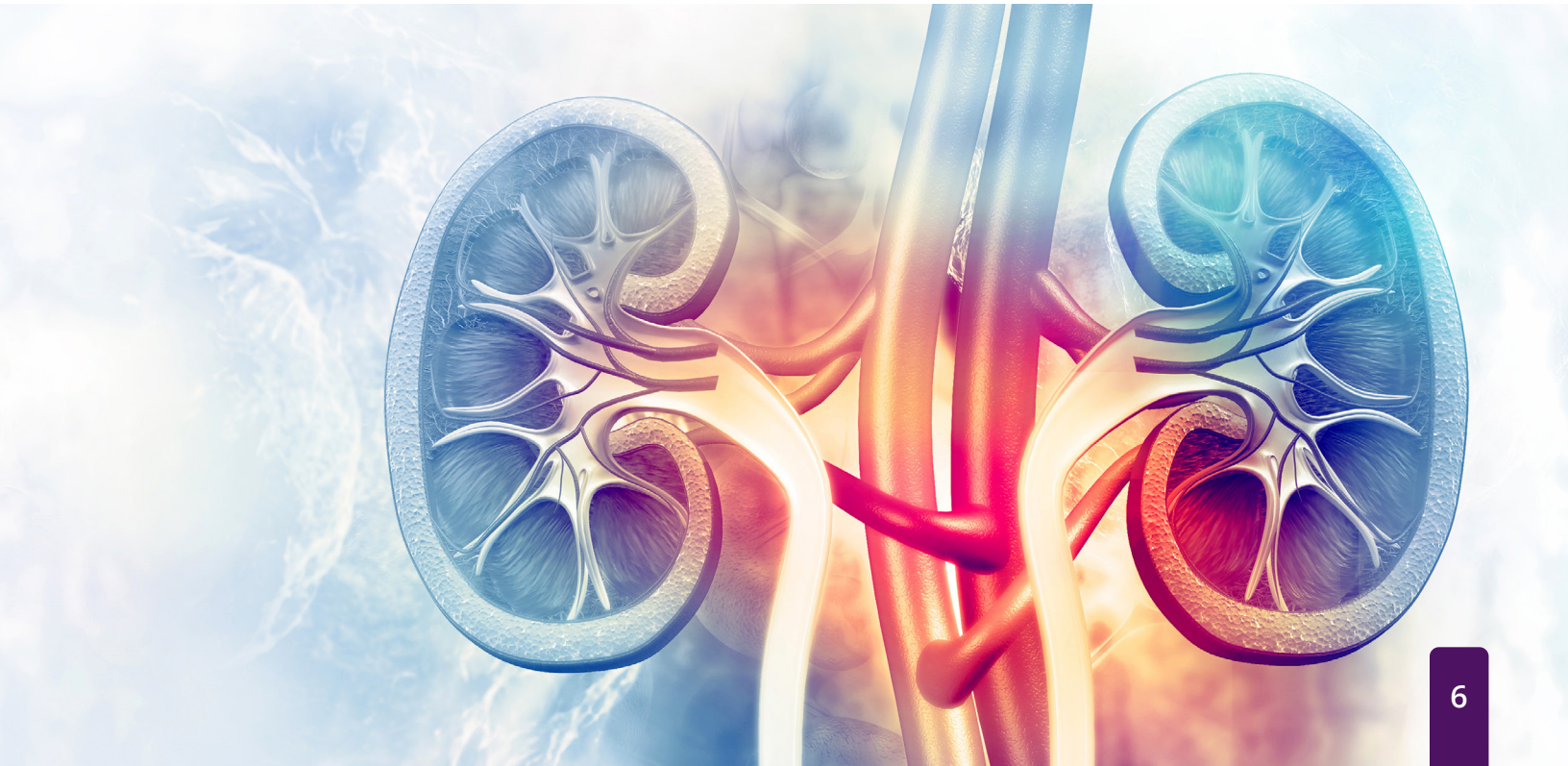
Milestones

- ✅ Completed chemical synthesis for animal studies in Q3 2021.
- ✅ Completed the non-clinical safety assessment studies in Q3 2022, required to initiate a Phase I study of UNI-494 in healthy volunteers.
- ✅ Initiated clinical development of UNI-494 in the United Kingdom (UK).
- ✅ Filed a Clinical Trial Application (CTA) with the Medicines and Healthcare Products Regulatory Agency (MHRA) to initiate a Phase 1 healthy volunteer study, with clearance in early 2023.

- Planning to file an Investigational New Drug (IND) application with the FDA for further clinical studies.

Cash Runway

As of March 31, 2024, Unicycive had $9.7 million in cash and cash equivalents. Following a $50 million private placement in March 2024, the company believes it has sufficient resources to fund planned operations into 2026. This cash position will support the filing of the Oxylanthanum Carbonate (OLC) NDA and initiate clinical trials for UNI-494.



STRONG MANAGEMENT TEAM

Shalabh Gupta, MD

Chief Executive Officer

Shalabh Gupta, M.D., Chief Executive Officer — Shalabh Gupta founded Unicycive and has served as its Chief Executive Officer, President, and Director since August 2016. Since June 2013, Dr. Gupta was also the founder and Chief Executive Officer of Globavir Biosciences, Inc., a company focused on commercializing novel therapeutics and powerful diagnostics for treating global infectious disease. Dr. Gupta previously served in various other capacities including founder and Chief Executive Officer of Biocycive Inc.; Strategy, Genentech Commercial at Genentech, Inc.; Equity Research, Pharmaceuticals at UBS Investment Bank; Attending Physician at NYU Medical Center; clinical faculty member at NYU School of Medicine; and Equity Research, Biotechnology at Rodman & Renshaw, LLC. In addition, he has served on the Board of Directors of Beall Center for Innovation and Entrepreneurship since 2018. Dr. Gupta has also served as an Advisor to SPARK, Stanford University School of Medicine, since 2012, a charter member of TiE, a not-for-profit network of entrepreneurs fostering entrepreneurship, mentoring, and education since 2013.

John Townsend, CPA

Chief Financial Officer

John Townsend, CPA, Chief Financial Officer — Mr. John Townsend is a certified public accountant (CPA) and serves as Chief Financial Officer at Unicycive Therapeutics Inc. Previously, he has served as Vice President Finance and Chief Accounting Officer in a consulting role for Unicycive. He has over 25 years of public and private company experience in industries including biotechnology, medical devices, and high-tech electronics manufacturing. Before joining Unicycive, Mr. Townsend worked at Guardion Health Sciences, a medical foods company from 2016 to 2020. From 2005 until 2015, he worked at Cytori Therapeutics, Inc., a stem cell therapy company. From 1996 to 2005, he worked at several high-tech companies.

Doug Jermasek, MBA

EVP, Corporate Strategy

Douglas Jermasek, MBA, EVP, Corporate Strategy — Douglas Jermasek joined Unicycive in 2021 as Executive Vice President, Corporate Strategy. Mr. Jermasek is a seasoned biopharmaceutical executive with over 25 years of commercial leadership experience in both U.S. and international markets. Most recently, he served as Senior Vice President, Marketing and Strategy, at Akebia Therapeutics, a role he assumed after the merger with Keryx Biopharmaceuticals. Previously, he spent over a decade at Genzyme (a Sanofi Company), with his tenure culminating as Senior Vice President and General Manager, Head of Renal Global Business Unit. In that role, he drove sales of over $1 billion, establishing Renvela® as the standard of care for the treatment of hyperphosphatemia for patients with chronic kidney disease (CKD) and achieving “blockbuster” status globally. Earlier, he held management positions of progressive responsibility at Intercept Pharmaceuticals,Prometheus Laboratories, Agouron Pharmaceuticals, and Abbott Laboratories.