UNICYCIVE THERAPEUTICS INC.

Nasdaq: UNCY

Unicycive Therapeutics develops novel treatments for kidney diseases. Lead drug, Renazorb (lanthanum dioxycarbonate) is an investigational phosphate binding agent developed for the treatment of hyperphosphatemia. UNI-494 is a novel new chemical entity that targets mitochondrial dysfunction being developed for the treatment of acute kidney injury.

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> INTERVIEW WITH EVP DOUG JERMASEK

Development Pipeline

Program	Indication	Pre-clinical	Phase 1	Phase 2	Phase 3	NDA
Renazorb	Hyperphosphatemia	→	→	→	→	*505b(2)
				*Phase 2 and Phase 3 trials not undertaken		
UNI-494	Acute Kidney Injury (AKI)	→				
UNI-494		→ Leverage AKI Data to enhance CKD development				

Addressing important patient needs in sizable markets within kidney disease

The kidneys perform critical functions, which include releasing hormones, regulating blood pressure, maintaining overall fluid balance, and filtering waste products. Kidney diseases are a manifestation of many other chronic medical problems, including diabetes, coronary artery diseases, high blood pressure to name a few. All of these chronic medical conditions continue to increase in terms of prevalence throughout our society and lead to kidney damage. In the U.S, there are currently ~32 million patients with chronic kidney disease (CKD), half a million per year have stage 5 CKD, which requires dialysis or kidney transplant. Hence, there is a sizable unmet need.

The key product that Unicycive is developing is a drug to address hyperphosphatemia in CKD. A patient is said to have hyperphosphatemia when phosphate in his/her blood is above a certain level. Hyperphosphatemia is common in patients with kidney disease, particularly those with late stage CKD, because the kidneys act as a filter for our blood. When the kidneys are damaged or diseased, they no longer perform this task well. Our body needs some phosphate to strengthen our bones and teeth, produce energy, and build cell membranes. Yet in larger-than-normal amounts, phosphate can cause bone and muscle problems and increase your risk for heart attacks and strokes. Hyperphosphatemia occurs in at least 80% of patients with Stage 5 CKD on dialysis.

Unicycive drug candidate Renazorb* (lanthanum dioxycarbonate) utilizes a proven mechanism of action

Phosphate binders (PB) are currently used to treat hyperphosphatemia. The PB market is a proven market that is $1billion in size in the U.S., and $2.5 billion globally. There are several different kinds of PBs and they all have their limitations, mostly in the form of pill burden, i.e., patients need to take too many large pills.

Source: Average daily dose: dailymed.nlm.nih.gov, Pill volumes and weights: Data on file, Unicycive Therapeutics, Product images are proportionally sized.

Renvela® is a registered trademark of Sanofi, Calphron® is a registered trademark of NEPHRO-TECH, INC., Auryxia® is a registered trademark of Akebia Therapeutics. Fosrenol™ is a trademark of Takeda Pharmaceutical Company Limited, Velphoro® is a registered trademark of Vifor Fresenius

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

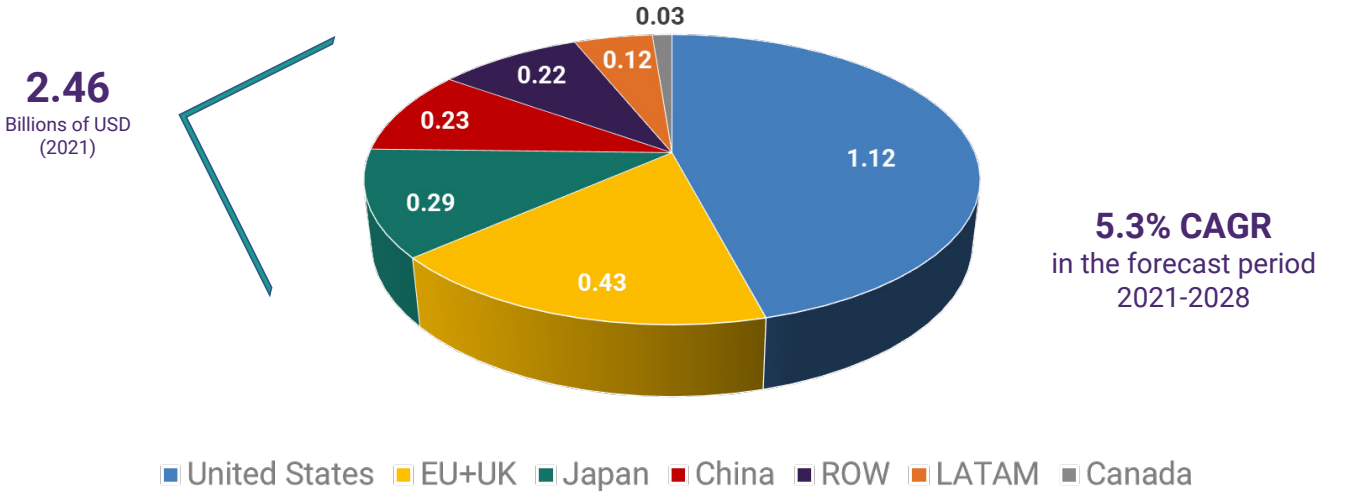
Unicycive's candidate drug Renazorb, developed under the company's proprietary nanotechnology, may significantly reduce patient's pill burden as the number and size of pills required is much less than current products on the market. Renazorb is a proprietary lanthanum-based and lanthanum is known to be one of the most potent phosphate lowering agents. If approved, patients will take one Renazorb pill three times a day with meals, versus other available options which require as many as 12 large pills per day.

Hyperphosphatemia market opportunity is sizable

The PB market generated ~$2.5B revenue globally in 2021 with > $1B sales from the U.S. Currently, Sevelamer is ~50% market share holder, 20% market share is calcium-based drugs, and Fosrenol, Auryxia, and Velphoro split the remaining 30% of the market. Renazorb has patent exclusivity through 2031 in the U.S. and the rest of the world giving it an attractive commercial runway.

1. Renazorb is protected by a family of U.S. patents and a related family of patents outside the U.S.
2. Both the U.S. patent family and the foreign patent family were filed in 2011, and the U.S. coverage has statutory expiry in 2031
3. Corresponding patents granted in Canada, Europe, Japan, China, Australia, and other countries also have statutory expiration dates in 2031

The diagram below summarizes the global market opportunity of Hyperphosphatemia



Unicycive owns worldwide rights to Renazorb

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

Renazorb is on a significantly de-risked regulatory pathway for approval

Unicycive received a response from the FDA in Q4 2021 in a Type C meeting that provided a clear path for filing an NDA through the expedited 505(b)(2) pathway for the U.S. approval (without the need of going through phase II and III), leveraging pre-clinical and clinical data from the existing approved lanthanum containing phosphate binder, Fosrenol. The company is conducting a bioequivalence (BE) study comparing phosphorus changes between Renazorb and Fosrenol in healthy volunteers, and a 6-month oral toxicity study in mice, and is securing required data on manufacturability and commercial supply readiness of the product. The enrollment of volunteers for BE study was completed in Q4 2022. The expected data readout by the end 2022 is viewed as a pivotal event.

From there, Unicycive can file an NDA in 2023, and with a year of review, the company can expect potential FDA approval in 2024.

Go-to-market strategy and partnerships

In Q4 2022, Unicycive entered an agreement granting exclusive rights to develop, market and commercialize Renazorb to Lee's Pharmaceutical (HK) Limited for Mainland China, Hong Kong and certain Asian markets. This agreement expands and accelerates the Renazorb opportunity in one of the largest and most important markets for patients through a local partner with deep domain expertise. The company received $1.0 million in upfront fee and is eligible for royalties on sales and other milestone payments. Unicycive will continue similar discussions with potential partners in Asia and Europe.

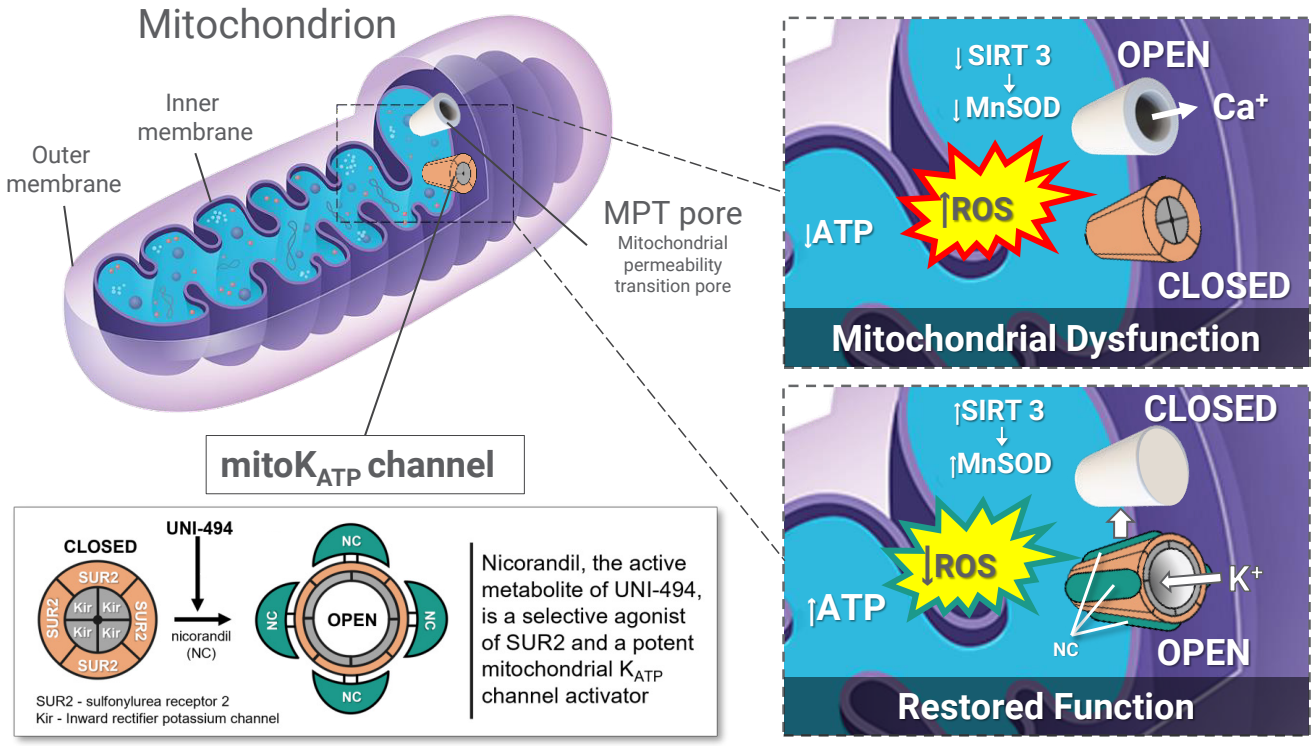
Unicycive's second program UNI-494 has gone under the radar, but a phase 1 clinical trial is slated to begin in early 2023

There is a significant unmet need for treating Acute Kidney Injury (AKI)

AKI is characterized by a sudden loss of kidney function. Persistent AKI is characterized by a continued decrease in urine output or increases in serum creatinine (as defined by KDIGO) beyond 48 hour from AKI onset up to 7 days. In most cases the damage to the kidney is irreversible, and the patient needs to have a renal transplant or go on dialysis. AKI mortality rate is 24% in adults, and there are no FDA approved drugs to treat AKI. Hence, there is a large unmet need for patients with AKI. UNI-494 is a patent-protected preclinical drug candidate that Unicycive is initially developing for the treatment of AKI with follow-on plans to treat chronic forms of kidney disease in the future.

How does UNI 494 work?

UNI-494 has a novel mechanism of action that works on mitochondria. Mitochondria are the energy powerhouse of cells. For the cell, which is a very small microcosm of the body, energy is important. Mitochondria play a key role in energy metabolism and energy management. Inflammation, a common culprit in the genesis of many chronic diseases including kidney disease, has negative effects on mitochondria disrupting energy metabolism leading to cell death. Inflammation triggers the opening of a specific pore (MPTP) on the inner mitochondrial membrane which causes swelling of the mitochondria and cell death. UNI-494 acts by closing MPTP pores thereby stabilizing and restoring mitochondrial function. Because mitochondrial dysfunction is involved in many disease processes, UNI-494 has potential application in numerous disease states.



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

UNI494 is undergoing many pre-clinical animal studies, and the company will initiate clinical development of UNI-494 in the United Kingdom (UK) to expedite clinical development and plans to file a clinical trial application to Medicines and Healthcare Products Regulatory Agency (MHRA) in the UK to initiate a Phase I healthy volunteer study and expects to be cleared by end of 2022. Also, the company plans to file an Investigational Drug Application (IND) with the FDA in early 2023 for a Phase I healthy volunteer study.

FDA Regulatory Strategy

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

Unique attributes for regulatory approval of UNI-494

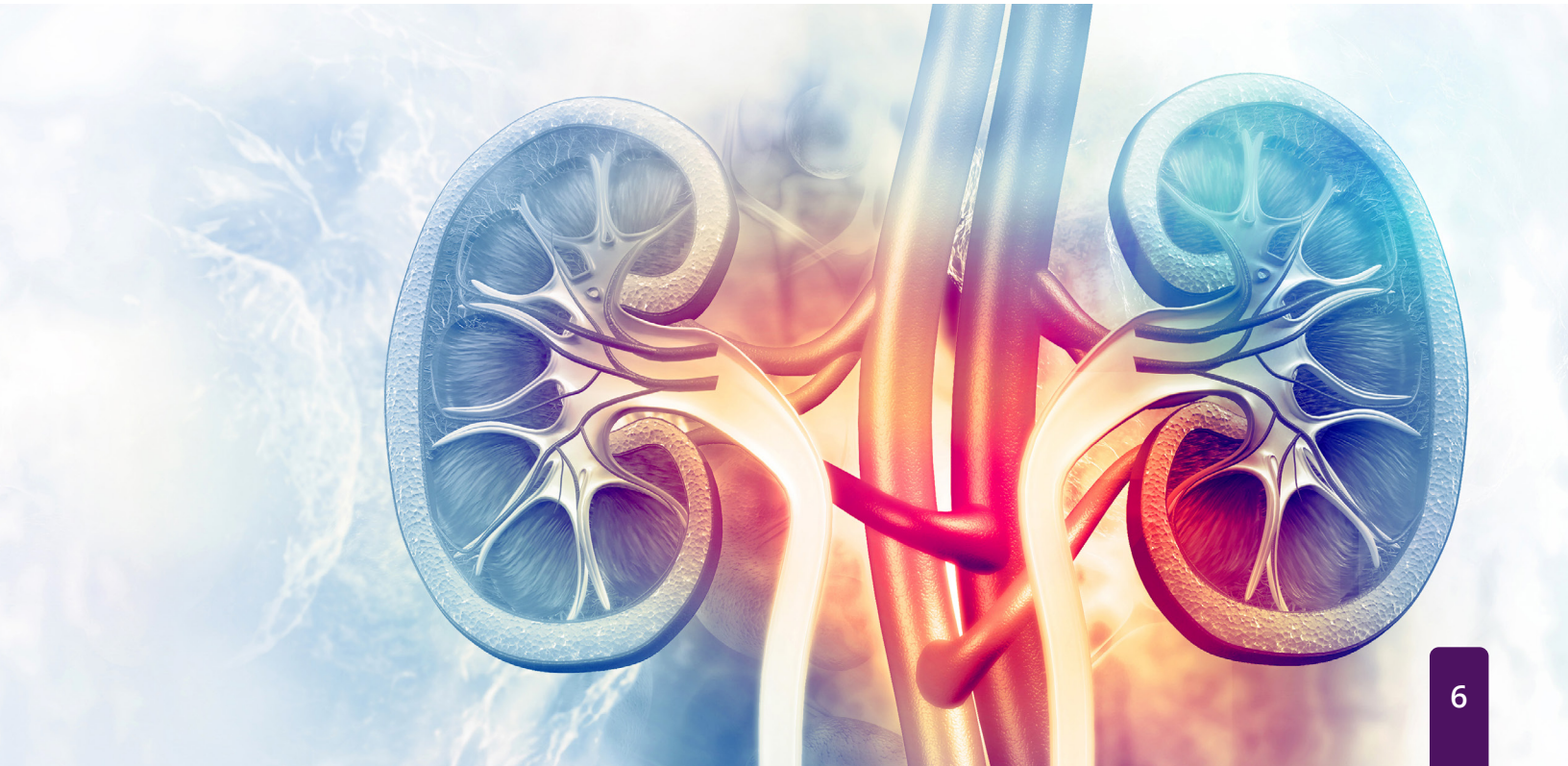
- Leverage pre-clinical and clinical data from nicorandil outside the U.S. with comparability package
- Design phase 2 clinical proof-of-concept trial in a more homogenous subset of AKI patients.

Milestones

- ✅ Completed chemical synthesis for animal studies in Q3 2021
- ✅ In Q3 2022, completed the non-clinical safety assessment studies required to initiate a Phase I study of UNI-494 in healthy volunteers.
- To initiate clinical development of UNI-494 in the United Kingdom (UK) to expedite clinical development
- To file a CTA to MHRA in the UK to initiate a Phase I healthy volunteer study and expects to be cleared by the end of the year
- To file an Investigational Drug Application (IND) with the FDA in early 2023 for a Phase I healthy volunteer study.

Sufficient cash runway to file Renazorb NDA and to initiate clinical trials for UNI-494

With ~$5 million expenses a quarter and $17 million in cash balance and potential future funding, Unicycive has enough funding to file Renazorb NDA and to 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.