

October 28, 2025



Unicycive Therapeutics Provides Update from FDA Type A Meeting and Expects to Resubmit OLC NDA Before Year-End

Cash runway into 2027, which is expected to support application resubmission, potential FDA approval, and launch of OLC

LOS ALTOS, Calif., Oct. 28, 2025 (GLOBE NEWSWIRE) -- Unicycive Therapeutics, Inc. (Nasdaq: UNCY), a clinical-stage biotechnology company developing therapies for patients with kidney disease (the Company or Unicycive), today announced an update from its meeting with the U.S. Food and Drug Administration (FDA) and timing of the resubmission of its New Drug Application (NDA) for Oxylanthanum Carbonate (OLC) following receipt of a Complete Response Letter (CRL) on June 30, 2025. The Type A FDA meeting was held to discuss the resolution of the single deficiency identified in the CRL related to the compliance status of a third-party manufacturing vendor. No other concerns have been identified to the Company, including pre-clinical, clinical, or safety data submitted as part of the NDA. Following receipt of the official meeting minutes from the Type A meeting and engaging in discussions with its third-party manufacturing vendor, the Company plans to resubmit the NDA for OLC by year-end.

"We are grateful for the highly constructive feedback and detailed meeting minutes we received from the FDA and look forward to resubmitting the NDA as we advance OLC toward potential approval," said Shalabh Gupta, MD, Chief Executive Officer of Unicycive. "Following our interactions with the FDA, we are very encouraged about the potential for a swift resolution of the issue raised in our CRL and we believe we are now on track to resubmit our NDA before the end of the year, which could lead to a PDUFA date in the first half of 2026. With over \$42 million on our balance sheet as of September 30, we have a cash runway into 2027, enabling us to work through the regulatory approval process and continue to advance preparations for potential OLC commercialization while focusing on our mission to deliver improved treatment options for patients with hyperphosphatemia on dialysis."

About Oxylanthanum Carbonate (OLC)

OLC is an investigational oral phosphate binder that leverages proprietary nanoparticle technology to deliver high phosphate binding potency, reducing the number and size of pills that patients must take to treat hyperphosphatemia in patients with chronic kidney disease (CKD) on dialysis. Its potential best-in-class profile may have meaningful patient adherence benefits over currently available treatment options as it requires a lower pill burden. Unicycive is seeking FDA approval of OLC via the 505(b)(2) regulatory pathway. The NDA submission package is based on data from three clinical studies (a Phase 1 study in healthy volunteers, a bioequivalence study in healthy volunteers, and a tolerability study of OLC in CKD patients on dialysis), multiple preclinical studies, and the chemistry,

manufacturing and controls (CMC) data. OLC is protected by a strong global patent portfolio including issued patents on composition of matter with exclusivity until 2031, and with the potential for patent term extension until 2035.

About Hyperphosphatemia

Hyperphosphatemia is a serious medical condition that occurs in nearly all patients with End Stage Renal Disease (ESRD). Annually there are over 450,000 individuals in the U.S. that require medication to control their phosphate levels.¹ Uncontrolled hyperphosphatemia is strongly associated with increased death and hospitalization for CKD patients on dialysis. Treatment of hyperphosphatemia is aimed at lowering serum phosphate levels via two means: (1) restricting dietary phosphorus intake; and (2) using, on a daily basis, and with each meal, oral phosphate binding drugs that facilitate fecal elimination of dietary phosphate rather than its absorption from the gastrointestinal tract into the bloodstream.

¹Flythe JE. Dialysis-Past, Present, and Future: A Kidney360 Perspectives Series. Kidney360. 2023 May 1;4(5):567-568. doi: 10.34067/KID.000000000000145. Epub 2023 Jun 29. PMID: 37229723; PMCID: PMC10371371.

About Unicycive Therapeutics

Unicycive Therapeutics is a biotechnology company developing novel treatments for kidney diseases. Unicycive's lead investigational treatment is oxylanthanum carbonate, a novel phosphate binding agent for the treatment of hyperphosphatemia in patients with chronic kidney disease who are on dialysis. Unicycive's second investigational treatment UNI-494 is intended for the treatment of conditions related to acute kidney injury. It has been granted orphan drug designation (ODD) by the FDA for the prevention of Delayed Graft Function (DGF) in kidney transplant patients and has completed a Phase 1 dose-ranging safety study in healthy volunteers.

Preliminary Financial Information

The preliminary financial information included in this press release is unaudited and is subject to completion of the Company's quarter-end closing procedures and further financial review. Actual results may differ from these estimates as a result of the completion of quarter-end closing procedures, review adjustments and other developments that may arise between now and the time such financial information for the period is finalized. As a result, these estimates are preliminary, may change and constitute forward-looking information and, as a result, are subject to risks and uncertainties. These preliminary estimates should not be viewed as a substitute for full financial statements prepared in accordance with United States generally accepted accounting principles, and they should not be viewed as indicative of our results for any future period. The Company's independent registered public accountants have not audited, reviewed, compiled, or performed any procedures with respect to these estimated financial results and, accordingly, do not express an opinion or any other form of assurance with respect to these preliminary estimates.

Forward-looking statements

Certain statements in this press release are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995. These statements may be identified using words such as "anticipate," "believe," "forecast," "estimated" and "intend" or other similar terms or expressions that concern Unicycive's expectations, strategy, plans or intentions. These forward-looking statements are based on Unicycive's current expectations and actual

results could differ materially. There are several factors that could cause actual events to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, clinical trials involve a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results; our clinical trials may be suspended or discontinued due to unexpected side effects or other safety risks that could preclude approval of our product candidates; risks related to business interruptions, which could seriously harm our financial condition and increase our costs and expenses; dependence on key personnel; substantial competition; uncertainties of patent protection and litigation; dependence upon third parties; risks related to failure to obtain FDA clearances or approvals and noncompliance with FDA regulations; risks related to our ability to file an NDA before the end of 2025, risk that we do not get a PDUFA date in the first half of 2026; the accuracy of our cash on hand at September 30, 2025 and risk that our cash runway does not extend into 2027. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the uncertainties related to market conditions and other factors described more fully in the section entitled 'Risk Factors' in Unicycive's Annual Report on Form 10-K for the year ended December 31, 2024, and other periodic reports filed with the Securities and Exchange Commission. Any forward-looking statements contained in this press release speak only as of the date hereof, and Unicycive specifically disclaims any obligation to update any forward-looking statement, whether as a result of new information, future events or otherwise.

Investor Contacts:**Kevin Gardner**

LifeSci Advisors

kgardner@lifesciadvisors.com**Media Contact:****Layne Litsinger**

Real Chemistry

llitsinger@realchemistry.com

SOURCE: Unicycive Therapeutics, Inc.



Source: Unicycive Therapeutics, Inc.