Unicycive Therapeutics Announces Resubmission of New Drug Application for Oxylanthanum Carbonate

Resubmission of NDA includes Chemistry, Manufacturing, and Controls (CMC) data from a new drug product manufacturing vendor



The resubmission package includes 12 months of OLC drug product stability data from the new manufacturing vendor

MOUNTAIN VIEW, CA, UNITED STATES, September 30, 2026 / EINPresswire.com/ -- Unicycive Therapeutics, Inc. ("Unicycive" or the "Company") (Nasdaq: UNCY), a clinical-stage biotechnology company developing therapies for patients with kidney disease, today announced the resubmission of its New Drug Application (NDA) for oxylanthanum carbonate (OLC), the Company's investigational oral phosphate binder for the treatment of hyperphosphatemia in patients with chronic kidney disease (CKD) on dialysis. The Company anticipates United States Food and Drug Administration (FDA) acceptance of the NDA within 30 days and a new assigned PDUFA date to be six months from the date of resubmission.

Unicycive Therapeutics, Inc. is a B2i Digital Featured Company. See the company's in-depth profile at: https://b2idigital.com/unicycive-therapeutics

The NDA resubmission includes CMC data from a new third-party drug product manufacturing vendor. The new vendor's facility was last inspected by the FDA in March 2024 and received "No Action Indicated" status, the highest FDA inspection classification indicating that a facility is in an acceptable state of current Good Manufacturing Practices (cGMP) compliance. The new vendor's

CMC data package includes technical specifications similar to the original third-party manufacturing vendor, and the new vendor has already produced OLC drug product and completed 12-month stability studies. In addition, the Company has provided additional in-vitro bridging data between the two vendors as recommended by the FDA in previous discussions.



Company anticipates FDA acceptance of the NDA within 30 days of resubmission; new assigned PDUFA date expected to be 6 months from resubmission

In June 2026, the Company received a Complete Response Letter (CRL) from the FDA regarding the first OLC NDA resubmission. The 2026 CRL cited the same third-party manufacturing deficiencies identified in a previous CRL issued in June 2025 to the initial NDA submission, as a result of the FDA not having conducted the reinspection of the original third-party manufacturing vendor. The FDA did not raise concerns regarding clinical efficacy or safety data and did not request additional data from the Company. The Company's original third-party manufacturing vendor has received written notification from the FDA that its facility inspection has been assigned, but the inspection has not yet occurred as of September 29, 2026. If the original third-party manufacturing vendor is inspected in the near term and deemed cGMP-compliant, the Company plans to seek FDA alignment on a shorter approval timeline for the OLC NDA resubmission. Unicycive intends to keep both drug product vendors to maintain supply chain redundancy.

> We believe this resubmission reflects an efficient path to potential approval and, if approved, a potentially faster path to bringing OLC to patients who need additional treatment options."
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> *Shalabh Gupta, M.D., Chief Executive Officer of Unicycive*

"We believe this resubmission reflects an efficient path to potential approval and, if approved, a potentially faster path to bringing OLC to patients who need additional treatment options," said Shalabh Gupta, M.D., Chief Executive Officer of Unicycive. "By adding an alternative primary manufacturing vendor, we are positioning the NDA for expedient review and potential approval. If the FDA's assigned inspection of the original vendor is completed favorably in the interim, that outcome could provide a potential timing benefit. We continue to advance commercial readiness activities in anticipation of a potential launch, with the goal of helping patients with CKD on dialysis who continue to struggle with hyperphosphatemia."

The NDA is supported by 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, along with multiple preclinical studies and CMC data.

As of June 30, 2026, unaudited cash, cash equivalents and marketable securities totaled $61.4 million, supporting continued OLC commercial launch preparation and an expected cash runway into the second half of 2027.

About Oxylanthanum Carbonate
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. 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.0000000000000145.

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. For more information, please visit Unicycive.com and follow us on LinkedIn and X.

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; our dependence on third parties for manufacturing; the possibility that FDA may require inspection of any vendor prior to approval, which could delay or prevent approval of our NDA; the risk that the original third-party manufacturing vendor’s reinspection may not occur within a timeframe that benefits our regulatory timeline, or may result in adverse findings; 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; market acceptance of our products; and risks related to failure to obtain FDA clearances or approvals and noncompliance with FDA regulations. 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, 2025, 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:
Unicycive Therapeutics
media@unicycive.com

Additional Contact

David Shapiro
B2i Digital, Inc.
+1 212-579-4844

david@b2idigital.com
Visit us on social media:
LinkedIn
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X
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