Unicycive Therapeutics Announces Second Quarter 2026 Financial Results and Provides Business Update

As of June 30, 2026, unaudited cash, cash equivalents, and marketable securities totaled $61.4 million, with expected runway into 2027

Company expects to resubmit New Drug Application (NDA) for oxylanthanum carbonate (OLC) assuming completion of successful inspection of third-party manufacturing vendor

MOUNTAIN VIEW, CA, UNITED STATES, August 12, 2026 /EINPresswire.com/ -- Unicycive Therapeutics, Inc. (Nasdaq: UNCY), a clinical-stage biotechnology company developing therapies for patients with kidney disease, today announced its financial results for the second quarter ended June 30, 2026, and provided a business update.

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

"We are focused on securing approval of oxylanthanum carbonate (OLC) and remain confident in the efficacy and safety of OLC and in its potential to improve care for patients with hyperphosphatemia on dialysis," said Shalabh Gupta, M.D., Chief Executive Officer of Unicycive. "The latest update from our third-party manufacturing vendor is that the U.S. Food and Drug Administration (FDA) has assigned a facility inspection. This marks a positive step forward, and our dialogue with the FDA on OLC labeling and packaging has been productive and continuous throughout this process. We are optimistic about a successful inspection of the third-party manufacturing facility, which would enable us to promptly resubmit the NDA. In the meantime, we are well positioned to launch OLC as quickly as possible following potential approval, and we are utilizing this time to continue to expand market awareness in preparation for the commercial success of OLC."

Key Highlights & Upcoming Milestones

FDA has assigned a facility inspection to third-party manufacturing vendor of OLC

• In June, the Company received a Complete Response Letter (CRL) from the FDA regarding the resubmitted NDA for OLC for the treatment of hyperphosphatemia in patients with chronic kidney disease on dialysis. The CRL cites the same third-party manufacturing deficiencies identified in a previous CRL issued in June 2025. The FDA has not raised any concerns regarding clinical efficacy or safety data, and no additional data was requested from the Company.
• The Company's third-party vendor has received written notification from the FDA that the facility inspection has been assigned, and the Company plans to provide an update following completion of the FDA inspection.
• In preparation for the potential launch of OLC, the Company continues to advance its commercial readiness initiatives. Unicycive is focused on optimizing patient access across all reimbursement settings and plans to support patients with dedicated access and reimbursement services through its UniSource™ reimbursement hub.
• The Company will also engage with the patient and clinical community at several medical meetings during the third quarter, including the 51st Annual American Association of Kidney Patients National Patient Meeting (September 11–13, Little Rock, Arkansas) and the 2026 Renal Healthcare Association Annual Conference (September 23–26, Savannah, Georgia).

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> *Shalabh Gupta, M.D., Chief Executive Officer of Unicycive*

Financial Results for the Quarter Ended June 30, 2026

Research and Development (R&D) expense was $2.8 million for the quarter ended June 30, 2026, compared to $1.8 million for the three months ended June 30, 2025. The increase was primarily driven by a $0.9 million increase in non-cash stock-based compensation, and an increase in consulting and professional fees of $0.1 million.

General and Administrative (G&A) expense was $7.4 million for the quarter ended June 30, 2026, compared to $5.2 million for the three months ended June 30, 2025. The increase was primarily

driven by a $1.4 million increase in non-cash stock-based compensation as well as an increase of $0.3 million in other labor costs. There was also an increase of $0.4 million related to commercial launch preparation.

Other income (expense) was $8.4 million for the quarter ended June 30, 2026, compared to $0.5 million income for the three months ended June 30, 2025, attributed primarily to an increase in the fair value of the Company's warrant liability.

Net loss attributable to common stockholders, basic and diluted, for the quarter ended June 30, 2026, was $(1.7) million, or $(0.06) per share of common stock, compared to $(6.5) million loss, or $(0.52) per share of common stock, for the three months ended June 30, 2025. The decreased net loss for the quarter ended June 30, 2026, was attributed primarily to a decrease in the fair value of the Company's warrant liability.

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 https://unicycive.com/

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; 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.

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