August 14, 2025

Unicycive Therapeutics Announces Second Quarter 2025 Financial Results and Provides Business Update

- Type A Meeting requested with U.S. Food and Drug Administration (FDA) for resolution of the Complete Response Letter (CRL) for oxylanthanum carbonate (OLC)

*- OLC pivotal study data, published in the*Clinical Journal of the American Society of Nephrology (CJASN)*, demonstrated OLC was well tolerated and enabled serum phosphate control in over 90% of patients with a low pill burden*

- Ended Q2 with $22.3 million of cash with expected runway into the second half of 2026

LOS ALTOS, Calif., Aug. 14, 2025 (GLOBE NEWSWIRE) -- Unicycive Therapeutics, Inc. ("Unicycive" or the "Company") (Nasdaq: UNCY), a clinical-stage biotechnology company developing therapies for patients with kidney disease, today announced its financial results for the three months ended June 30, 2025, and provided a business update.

"Our team has made great progress in the second quarter, and we have requested a Type A meeting with the FDA to resolve the CRL and obtain regulatory approval. We believe we have built multiple approaches to correct the deficiency noted for our third-party manufacturing vendor, which was unrelated to OLC," said Shalabh Gupta, M.D., Chief Executive Officer of Unicycive. "Meanwhile, the recently published pivotal trial data in CJASN continue to highlight OLC's best-in-class potential. Given the high rates of patient non-compliance with existing phosphate lowering therapies, we remain fully committed to meeting this clear need for improved treatment options for managing hyperphosphatemia in dialysis patients."

Key Highlights & Upcoming Milestones

- Unicycive has requested a Type A meeting with the FDA to discuss resolution of the CRL received in June in regard to its New Drug Application for OLC. Typically, Type A meetings are granted by the FDA within 30 days of the request. The Company plans to provide an investor update in the third quarter once it has received the FDA's written feedback.
- In July, the Company announced the publication of pivotal clinical study data describing the safety and tolerability of OLC in CKD patients on dialysis in *CJASN*. Data demonstrated that OLC was well tolerated, with over 90% of patients achieving effective phosphate control with most individuals needing no more than one tablet per meal.

Financial Results for the Quarter Ended June 30, 2025

Research and Development (R&D) expenses were $1.8 million for the three months ended June 30, 2025, compared to $4.9 million for the three months ended June 30, 2024. The decrease in research and development expenses was primarily due to decreased drug development costs.

General and Administrative (G&A) expenses were $5.2 million for the three months ended June 30, 2025, compared to $2.5 million for the three months ended June 30, 2024. The increase was primarily due to increased consulting and professional services related to our commercial launch preparation.

Other income was $0.5 million for the three months ended June 30, 2025, compared to other income of $17.3 million for the three months ended June 30, 2024, primarily due to the change in fair value of our warrant liability.

Net loss attributable to common stockholders for the three months ended June 30, 2025, was $6.4 million, compared to net income attributable to common stockholders of $3.0 million for the three months ended June 30, 2024. The increased net loss for the three-month period ended June 30, 2025 was primarily due to the change in fair value of our warrant liability.

As of June 30, 2025, cash and cash equivalents totaled $22.3 million. The Company believes that it has sufficient resources to fund operations into the second half of 2026.

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 about Unicycive, 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; risks related to business interruptions, which could seriously harm our financial condition and increase our costs and expenses; our need to raise substantial additional capital in the

future to fund our continuing operations and the development and commercialization of our current product candidates and future product candidates; dependence on key personnel; substantial competition; uncertainties of patent protection and litigation; dependence upon third parties; risks related to delays in obtaining or failure to obtain FDA clearances or approvals and noncompliance with FDA regulations; and our failure, or the failure of our third-party manufacturers, or their subcontractors, to comply with cGMPs or other applicable regulations, which could result in sanctions being imposed on us or the manufacturers, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates, operating restrictions and criminal prosecutions, any of which could adversely affect supplies of our product candidates and harm our business and results of operations. 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.

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SOURCE: Unicycive Therapeutics, Inc.

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Balance Sheets
(in thousands, except for share and per share amounts)

	As of December 31, 2024	As of June 30, 2025 (Unaudited)
Assets		
Current assets:		
Cash	$ 26,142	$ 22,327
Prepaid expenses and other current assets	4,806	7,199
Total current assets	30,948	29,526
Right of use asset, net	645	386
Property and equipment, net	75	83
Total assets	$ 31,668	$ 29,995
Liabilities and stockholders' equity		
Current liabilities:		

Accounts payable	$ 1,058	$ 775
Accrued liabilities	3,562	2,168
Warrant liability	18,936	10,214
Operating lease liability - current	564	409
Total current liabilities	24,120	13,566
Operating lease liability - long term	117	-
Total liabilities	24,237	13,566
Commitments and contingencies		
Stockholders' equity:		
Series A-2 Prime preferred stock, $0.001 par value per share - 21,400 Series A-2 Prime shares authorized at December 31, 2024 and June 30, 2025; 6,150.21 and 5,464.21 Series A-2 Prime shares issued and outstanding at December 31, 2024, and June 30, 2025, respectively	-	-
Series B-2 preferred stock, $0.001 par value per share - 50,000 Series B-2 shares authorized at December 31, 2024 and June 30, 2025; 3,000 and zero Series B-2 shares issued and outstanding at December 31, 2024, and June 30, 2025, respectively	-	-
Preferred stock: $0.001 par value per share - 10,000,000 shares authorized at December 31, 2024 and June 30, 2025; zero shares issued and outstanding at December 31, 2024, and June 30, 2025	-	-
Common stock, $0.001 par value per share - 400,000,000 shares authorized at December 31, 2024 and June 30, 2025; 11,384,236 and 14,111,852 shares issued and outstanding at December 31, 2024, and June 30, 2025, respectively	114	122
Additional paid-in capital	108,587	123,454
Accumulated deficit	(101,270)	(107,147)
Total stockholders' equity	7,431	16,429
Total liabilities and stockholders' equity	$ 31,668	$ 29,995

Unicycive Therapeutics, Inc.

Statements of Operations
(in thousands, except for share and per share amounts)
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2025	2024	2025
Operating expenses:				
Research and development	$ 4,868	$ 1,750	$ 11,681	$ 3,936
General and administrative	2,533	5,213	4,925	11,031
Total operating expenses	7,401	6,963	16,606	14,967
Loss from operations	(7,401)	(6,963)	(16,606)	(14,967)
Other income (expenses):				
Interest income	462	155	532	381
Interest expense	(16)	(13)	(36)	(13)
Change in fair value of warrant liability	16,810	374	5,002	8,722
Total other income (expenses)	17,256	516	5,498	9,090
Net income (loss)	9,855	(6,447)	(11,108)	(5,877)
Dividend to Series B-1 preferred stockholders	(887)	-	(1,095)	-
Net income attributable to participating securities	(5,925)	-	-	-
Net income (loss) attributable to common stockholders	$ 3,043	$ (6,447)	$ (12,203)	$ (5,877)
Net income (loss) per share attributable to common stockholders, basic	$ 0.80	$ (0.52)	$ (3.35)	$ (0.49)
Net loss per share attributable to common stockholders, diluted	$ (1.50)	$ (0.52)	$ (3.35)	$ (0.49)
Weighted-average shares outstanding used in computing net income (loss) per share, basic	3,791,481	12,302,059	3,639,800	11,993,663
Weighted-average shares outstanding used in computing net loss per share, diluted	9,405,285	12,302,059	3,639,800	11,993,663

Source: Unicycive Therapeutics, Inc.