November 16, 2026

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

- *New Drug Application (NDA) for oxylanthanum carbonate (OLC) accepted by the U.S. Food and Drug Administration (FDA), with an assigned Prescription Drug User Fee Act (PDUFA) date of March 25, 2027*

- *As of September 30, 2026, unaudited cash, cash equivalents, and marketable securities totaled $59 million, with expected runway beyond 2027, including the cost of potential OLC launch*

MOUNTAIN VIEW, Calif., Nov. 16, 2026 (GLOBE NEWSWIRE) -- Unicycive Therapeutics, Inc. ("Unicycive" or the "Company") (Nasdaq: UNCY), a biotechnology company developing therapies for patients with kidney disease, today announced its financial results for the third quarter ended September 30, 2026, and provided a business update.

"We believe that the FDA's acceptance of our NDA resubmission for OLC marks an important step toward our goal of bringing this much-needed treatment to patients," said Shalabh Gupta, M.D., Chief Executive Officer of Unicycive. "With a PDUFA target action date of March 25, 2027, our focus now is on continuing to advance launch preparations in parallel with the FDA's review in order to support a potential launch."

Key Highlights & Upcoming Milestones

- **OLC NDA Resubmission:** In October, the Company announced that the FDA has accepted the resubmission of its NDA for OLC and set a PDUFA target action date of March 25, 2027. The NDA was resubmitted following a Complete Response Letter (CRL) received in June 2026, which cited deficiencies previously identified at the original Drug Product (DP) vendor. The June 2026 CRL did not raise concerns regarding clinical efficacy or safety data or request additional data from the Company. The resubmitted NDA remains subject to FDA review.
    - The NDA resubmission includes CMC data from a new DP manufacturing vendor. The new vendor's facility was last inspected by the FDA in March 2024 and received "No Action Indicated" status. The Company does not know whether the FDA will decide to conduct a pre-approval inspection of this DP vendor.
    - The original DP vendor was recently inspected by the FDA. If the FDA finds that its facility complies with current Good Manufacturing Practice (cGMP), the Company plans to align with the FDA on whether that determination could shorten its review timeline and potential approval.

- **Commercial Readiness:** In preparation for the potential launch of OLC, Unicycive

continues to advance its commercial readiness initiatives:

- Discussions with dialysis organizations as part of the OLC launch planning.
- The Company is in active discussions with key commercial leaders, with plans to bring them on board in the first quarter of 2027 and, if OLC is approved by the FDA, expects to hire an optimized sales force to target the physician prescriber base.
- Unicycive is also focused on optimizing patient access across all reimbursement settings and plans to provide dedicated access and services through its UniSource™ support hub.
  On October 28, 2026, the Centers for Medicare & Medicaid Services (CMS) issued its calendar year 2027 End-Stage Renal Disease Prospective Payment System final rule, establishing permanent phosphate binder funding within the dialysis bundled payment through a $12.85 per-treatment addition to the base rate effective January 1, 2027, following the expiration of separate transitional payments for existing binders. CMS also finalized a hyperphosphatemia clinical quality measure beginning with payment year 2029, based on 2027 performance, reinforcing the importance of sustained phosphorus control. Unicycive believes that these changes create favorable commercial launch conditions for OLC, if approved. Subject to FDA approval and CMS confirmation of Transitional Drug Add-on Payment Adjustment (TDAPA) eligibility, OLC could potentially qualify for two years of separate reimbursement at 100% of average sales price while dialysis providers continue to receive the new funding for binders embedded in the base rate.

- **TDAPA Eligibility:** Unicycive believes OLC meets the criteria for the TDAPA upon FDA approval:
  - OLC qualified for a 505(b)(2) regulatory path because it contains an active moiety (lanthanum) that was previously approved; however, OLC contains a new active ingredient, oxylanthanum carbonate, that was not previously approved. The Company believes this supports Type 2 NDA classification under the FDA's Manual of Policies and Procedures 5018.2, NDA Classification Codes.
  - The determination of OLC's NDA classification rests solely with the FDA and remains subject to the agency's determination of NDA classification at the time of approval. The Company believes OLC, if approved, would qualify for TDAPA, subject to meeting applicable CMS requirements.

Financial Results for the Quarter Ended September 30, 2026

Research and Development (R&D) expense was $2.2 million for the quarter ended September 30, 2026, compared to $3.0 million for the three months ended September 30, 2025. The decrease was primarily driven by a $1.2 million decrease in developments costs, which was partially offset by an increase in non-cash stock-based compensation of $0.5 million.

General and Administrative (G&A) expense was $6.6 million for the quarter ended September 30, 2026, compared to $4.4 million for the three months ended September 30, 2025. The increase was primarily driven by a $0.6 million increase in non-cash stock-based compensation as well as an increase of $0.2 million in other labor costs. There was also an

increase of $1.4 million related to commercial launch preparation.

Other income (expense) was $1.8 million for the quarter ended September 30, 2026, compared to $1.3 million income for the three months ended September 30, 2025, attributed primarily to the change in fair value of the Company's warrant liability.

Net loss attributable to common stockholders, basic and diluted, for the quarter ended September 30, 2026, was $(7.0) million, or $(0.25) per share of common stock, compared to $(6.0) million, or $(0.33) per share of common stock, for the three months ended September 30, 2025. The increased net loss for the quarter ended September 30, 2026, was attributed primarily to an increase in commercial launch expenses.

Cash, cash equivalents and marketable securities were approximately $59 million as of September 30, 2026, with expected runway beyond 2027, including anticipated increased expenses related to the launch of OLC should it receive approval.

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; 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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SOURCE: Unicycive Therapeutics, Inc.

Unicycive Therapeutics, Inc.
Balance Sheets
(in thousands, except for share and per share amounts)

	As of December 31, 2025	As of September 30, 2026
Assets		(Unaudited)
Current assets:		
Cash	$ 29,198	$ 41,966
Prepaid expenses and other current assets	7,692	10,187
Marketable securities	12,071	17,006
Total current assets	48,961	69,159
Right of use asset, net	108	519
Property and equipment, net	66	255
Total assets	$ 49,135	$ 69,933
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 383	$ 1,030
Accrued liabilities	1,523	3,380
Warrant liability	16,915	12,377
Operating lease liability - current	117	522
Total current liabilities	18,938	17,309
Operating lease liability - long term	-	-
Total liabilities	18,938	17,309
Commitments and contingencies		
Stockholders' equity:		
Series A-2 Prime preferred stock, $0.001 par value per share - 21,388.01 Series A-2 Prime shares authorized at December 31, 2025, and September 30, 2026; 2,265 and zero Series A-2 Prime shares issued and outstanding at December 31, 2025, and September 30, 2026, respectively	-	-
Series B-2 preferred stock, $0.001 par value per share - 50,000 Series B-2 shares authorized at December 31, 2025, and September 30, 2026; zero Series B-2 shares issued and outstanding at December 31, 2025, and September 30, 2026	-	-
Preferred stock, $0.001 par value per share- 10,000,000 shares authorized at December 31, 2025, and June 30, 2026; zero shares issued and outstanding at December 31, 2025, and June 30, 2026	-	-

Common stock, $0.001 par value per share - 400,000,000 shares authorized at December 31, 2025, and September 30, 2026; 22,114,245 and 29,110,352 shares issued and outstanding at December 31, 2025, and September 30, 2026, respectively	22	29
Accumulated other comprehensive loss	(1)	(26)
Additional paid-in capital	158,001	201,988
Accumulated deficit	(127,825)	(149,367)
Total stockholders' equity	30,197	52,624
Total liabilities and stockholders' equity	$ 49,135	$ 69,933

Unicycive Therapeutics, Inc.
Statements of Operations and Comprehensive Loss
(in thousands, except for share and per share amounts)
(Unaudited)

	Three Months Ended September 30,	
	2025	**2026**
Operating expenses:		
Research and development	$ 2,964	$ 2,246
General and administrative	4,378	6,595
Total operating expenses	7,342	8,841
Loss from operations	(7,342)	(8,841)
Other income (expenses):		
Interest income	279	503
Interest expense	(15)	-
Change in fair value of warrant liability	1,067	1,341
Total other income (expenses)	1,331	1,844
Net loss	(6,011)	(6,997)
Other comprehensive loss:		
Unrealized loss on marketable securities, net	-	(3)
Net comprehensive loss	$ (6,011)	$ (7,000)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.33)	$ (0.25)
Weighted-average shares outstanding used in computing net loss per share	18,065,389	28,270,842

Source: Unicycive Therapeutics, Inc.