UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **November 16, 2026**

Unicycive Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-40582**	**81-3638692**
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	IRS Employer Identification No.)

4300 El Camino Real, Suite 210
Los Altos, CA 94022
(Address of principal executive offices)

Registrant's telephone number, including area code: **(650) 351-4495**

(Former name or former address, if changed since last report)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class:	**Trading Symbol(s)**	**Name of each exchange on which registered:**
Common Stock	UNCY	Nasdaq Capital Market

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communication pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter). Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Conditions.

On November 16, 2026, Unicycive Therapeutics, Inc. issued a press release announcing its financial results for the third quarter ended September 30, 2026 and provided a business update. A copy of the press release is furnished as Exhibit 99.1 to this Form 8-K.

The information disclosed under this Item 2.02, including Exhibit 99.1 hereto, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall it be incorporated by reference into any registration statement or other document pursuant to the Securities Act of 1933, as amended, except as expressly set forth in such filing.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits.

99.1	Press Release of Unicycive Therapeutics, Inc. dated November 16, 2026.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: November 16, 2026

UNICYCIVE THERAPEUTICS, INC.

By: /s/ Shalabh Gupta
Shalabh Gupta
Chief Executive Officer

Exhibit 99.1

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 a potential OLC launch*

MOUNTAIN VIEW, Calif., November 16, 2026 — 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 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 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, offering potential economic advantage to providers.

- **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.