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): **October 28, 2025**

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 Alto, 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 Condition

On October 28, 2025, Unicycive Therapeutics, Inc. (the "Company") issued a press release that included information with respect to certain preliminary, unaudited financial results of the Company.

While the Company has not finalized its full financial results for the quarter ended September 30, 2025, the Company expects to report that it had approximately $42 million of cash and cash equivalents as of September 30, 2025. This estimate is preliminary and is subject to change pending the actual results of, and completion of, the Company's condensed consolidated financial statements for the quarter ending September 30, 2025. Additional information and disclosures would be required for a more complete understanding of the Company's financial position and results of operations as of September 30, 2025. The Company's independent registered public accounting firm has not reviewed or performed any procedures with respect to this preliminary information and, accordingly, does not express an opinion or any other form of assurance about them. Complete quarterly results will be included in the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2025.

The information in this Item 2.02 is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the Exchange Act), or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended (the Securities Act), nor shall it be deemed incorporated by reference in any filing under the Securities Act or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 8.01. Other Events

On October 28, 2025, the Company issued a press release announcing an update from its meeting with the U.S. Food and Drug Administration and timing of the resubmission of its New Drug Application for Oxylanthanum Carbonate following receipt of a Complete Response Letter on June 30, 2025. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits.

99.1	Press Release of Unicycive Therapeutics, Inc. dated October 28, 2025.

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: October 28, 2025

UNICYCIVE THERAPEUTICS, INC.

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

Exhibit 99.1

Unicycive Therapeutics Provides Update from FDA Type A Meeting and Expects to Resubmit OLC NDA Before Year-End

- *Cash runway into 2027, which is expected to support application resubmission, potential FDA approval, and launch of OLC*

LOS ALTOS, California, October 28, 2025 -- Unicycive Therapeutics, Inc. (Nasdaq: UNCY), a clinical-stage biotechnology company developing therapies for patients with kidney disease (the Company or Unicycive), today announced an update from its meeting with the U.S. Food and Drug Administration (FDA) and timing of the resubmission of its New Drug Application (NDA) for Oxylanthanum Carbonate (OLC) following receipt of a Complete Response Letter (CRL) on June 30, 2025. The Type A FDA meeting was held to discuss the resolution of the single deficiency identified in the CRL related to the compliance status of a third-party manufacturing vendor. No other concerns have been identified to the Company, including pre-clinical, clinical, or safety data submitted as part of the NDA. Following receipt of the official meeting minutes from the Type A meeting and engaging in discussions with its third-party manufacturing vendor, the Company plans to resubmit the NDA for OLC by year-end.

"We are grateful for the highly constructive feedback and detailed meeting minutes we received from the FDA and look forward to resubmitting the NDA as we advance OLC toward potential approval," said Shalabh Gupta, MD, Chief Executive Officer of Unicycive. "Following our interactions with the FDA, we are very encouraged about the potential for a swift resolution of the issue raised in our CRL and we believe we are now on track to resubmit our NDA before the end of the year, which could lead to a PDUFA date in the first half of 2026. With over $42 million on our balance sheet as of September 30, we have a cash runway into 2027, enabling us to work through the regulatory approval process and continue to advance preparations for potential OLC commercialization while focusing on our mission to deliver improved treatment options for patients with hyperphosphatemia on dialysis."

About Oxylanthanum Carbonate (OLC)

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. The NDA submission package is based on 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), multiple preclinical studies, and the chemistry, manufacturing and controls (CMC) data. 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.

1 Flythe JE. Dialysis-Past, Present, and Future: A Kidney360 Perspectives Series. Kidney360. 2023 May 1;4(5):567-568. doi: 10.34067/KID.0000000000000145. Epub 2023 Jun 29. PMID: 37229723; PMCID: PMC10371371.

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.

Preliminary Financial Information

The preliminary financial information included in this press release is unaudited and is subject to completion of the Company's quarter-end closing procedures and further financial review. Actual results may differ from these estimates as a result of the completion of quarter-end closing procedures, review adjustments and other developments that may arise between now and the time such financial information for the period is finalized. As a result, these estimates are preliminary, may change and constitute forward-looking information and, as a result, are subject to risks and uncertainties. These preliminary estimates should not be viewed as a substitute for full financial statements prepared in accordance with United States generally accepted accounting principles, and they should not be viewed as indicative of our results for any future period. The Company's independent registered public accountants have not audited, reviewed, compiled, or performed any procedures with respect to these estimated financial results and, accordingly, do not express an opinion or any other form of assurance with respect to these preliminary estimates.

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; dependence on key personnel; substantial competition; uncertainties of patent protection and litigation; dependence upon third parties; risks related to failure to obtain FDA clearances or approvals and noncompliance with FDA regulations; risks related to our ability to file an NDA before the end of 2025, risk that we do not get a PDUFA date in the first half of 2026; the accuracy of our cash on hand at September 30, 2025 and risk that our cash runway does not extend into 2027 . 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.