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 12, 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 Conditions.

On November 12, 2025, Unicycive Therapeutics, Inc. issued a press release announcing its financial results for the three months ended September 30, 2025 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 12, 2025.
104	Cover page interactive data file (formatted as Inline XBRL)

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 12, 2025

UNICYCIVE THERAPEUTICS, INC.

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

Exhibit 99.1

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

- Remain on track to resubmit the New Drug Application (NDA) for oxylanthanum carbonate (OLC) by year end

- Presented new analysis of OLC data at American Society of Nephrology (ASN) which demonstrates that OLC significantly reduced pill burden in terms of both pill volume (7x) and pill count (2x) compared to currently available phosphate binders

- Ended Q3 with $42.7 million of cash with expected runway into 2027

LOS ALTOS, California, November 12, 2025 -- 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 September 30, 2025, and provided a business update.

"With a continued commitment to advancing OLC, we are poised to resubmit the NDA for OLC by the end of the year, following positive discussions with the FDA and our third-party manufacturing vendor," said Shalabh Gupta, M.D., Chief Executive Officer of Unicycive. "Our focus has always been on enhancing the lives of people with hyperphosphatemia, as evidenced by the promising new data presented at ASN Kidney Week 2025 that showcase OLC's differentiated clinical profile and reduced pill burden compared to currently available phosphate binders. With a cash runway into 2027, we are well positioned to complete the regulatory approval process and prepare for the potential launch of OLC next year, marking significant progress in advancing our mission to deliver improved treatment options for patients on dialysis."

Key Highlights & Upcoming Milestones

- Unicycive announced its intention to resubmit the NDA for OLC by year-end, with the potential to receive a new Prescription Drug User Fee Act (PDUFA) date in the first half of 2026. This announcement followed a Type A meeting with the U.S. Food and Drug Administration FDA. During the meeting, the FDA discussed the single deficiency noted in the CRL concerning a third-party manufacturing vendor, with no additional issues identified to the Company, including preclinical, clinical, or safety data. Following the receipt of our CRL in June, our third-party manufacturing vendor was recently inspected by EU regulatory authorities with no deficiencies identified. After the Type A meeting and discussions with our third party manufacturing vendor, we remain optimistic about the resolution of the CRL deficiency and our ability to refile.

- Company presented new data on OLC at the American Society of Nephrology (ASN) Kidney Week 2025. Findings from the open-label pivotal trial demonstrate that OLC significantly reduced pill burden compared to pre-trial phosphate binder therapy, with a 7-fold decrease in pill volume and a 2-fold reduction in pill count.

Financial Results for the Quarter Ended September 30, 2025

Research and Development (R&D) expenses were $3.0 million for the three months ended September 30, 2025, compared to approximately $3.1 million for the three months ended September 30, 2024. The decrease in research and development expenses was primarily due to a $235,000 decrease in professional services and drug development costs, partially offset by increases in labor, travel, and other costs of $154,000.

General and Administrative (G&A) expenses were $4.4 million for the three months ended September 30, 2025, compared to $3.2 million for the three months ended September 30, 2024. The increase was primarily due to a $0.6 million increase in labor costs and a $0.5 million increase in consulting and professional services.

Other income was $1.3 million for the three months ended September 30, 2025, compared to other income of $2.2 million for the three months ended September 30, 2024. The decrease was primarily due to the change in fair value of our warrant liability.

Net loss attributable to common stockholders for the three months ended September 30, 2025, was $6.0 million, compared to net loss attributable to common stockholders of $4.1 million for the three months ended September 30, 2024. The increased net loss for the three-month period ended September 30, 2025 was primarily due to increased labor and professional services costs as well as the change in fair value of our warrant liability.

As of September 30, 2025, cash and cash equivalents totaled $42.7 million. The Company believes that it has a cash runway into 2027.

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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Unicycive Therapeutics, Inc.

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

	As of December 31, 2024	As of September 30, 2025 (Unaudited)
Assets		
Current assets:		
Cash	$ 26,142	$ 42,695
Prepaid expenses and other current assets	4,806	7,592
Total current assets	30,948	50,287
Right of use asset, net	645	249
Property and equipment, net	75	75
Total assets	$ 31,668	$ 50,611
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,058	$ 957
Accrued liabilities	3,562	2,762
Warrant liability	18,936	9,147
Operating lease liability - current	564	265
Total current liabilities	24,120	13,131
Operating lease liability - long term	117	-
Total liabilities	24,237	13,131
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 September 30, 2025; 6,150.21 and 2,265 Series A-2 Prime shares issued and outstanding at December 31, 2024, and September 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 September 30, 2025; 3,000 and zero Series B-2 shares issued and outstanding at December 31, 2024, and September 30, 2025, respectively	-	-
Preferred stock: $0.001 par value per share - 10,000,000 shares authorized at December 31, 2024 and September 30, 2025; zero shares issued and outstanding at December 31, 2024, and September 30, 2025	-	-
Common stock, $0.001 par value per share - 400,000,000 shares authorized at December 31, 2024 and September 30, 2025; 11,384,236 and 20,850,363 shares issued and outstanding at December 31, 2024, and September 30, 2025, respectively	11	21
Additional paid-in capital	108,690	150,617
Accumulated deficit	(101,270)	(113,158)
Total stockholders' equity	7,431	37,480
Total liabilities and stockholders' equity	$ 31,668	$ 50,611

Unicycive Therapeutics, Inc.

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

	Three Months Ended September 30,	
	2024	**2025**
Operating expenses:		
Research and development	$ 3,045	$ 2,964
General and administrative	3,206	4,378
Total operating expenses	6,251	7,342
Loss from operations	(6,251)	(7,342)
Other income (expenses):		
Interest income	416	279
Interest expense	(15)	(15)
Change in fair value of warrant liability	1,754	1,067
Total other income (expenses)	2,155	1,331
Net loss	(4,096)	(6,011)
Dividend to Series B-1 preferred stockholders	-	-
Net loss attributable to common stockholders	$ (4,096)	$ (6,011)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.46)	$ (0.33)
Weighted-average shares outstanding used in computing net loss per share, basic and diluted	8,894,321	18,065,389