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): **May 14, 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 fling 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 May 14, 2025, Unicycive Therapeutics, Inc. issued a press release announcing its financial results for the three months ended March 31, 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 May 14, 2025.
104	Cover Page Interactive Data File (embedded within Inline XBRL document).

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: May 14, 2025

UNICYCIVE THERAPEUTICS, INC.

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

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

- *Oxylanthanum carbonate (OLC) New Drug Application (NDA) for hyperphosphatemia in chronic kidney disease patients on dialysis under review by FDA with PDUFA target action date of June 28, 2025; ongoing commercial planning in preparation for anticipated commercial launch in late 2025*

- *New data from patient surveys and patient-reported outcomes studies highlight adherence challenges for patients with hyperphosphatemia on dialysis and emphasize the market potential of OLC.*

LOS ALTOS, California, May 14, 2025 -- Unicycive Therapeutics, Inc. (Nasdaq: UNCY), a clinical-stage biotechnology company developing therapies for patients with kidney disease, today announced its financial results for the three months ended March 31, 2025, and provided a business update.

"We are making incredible strides as we prepare for the potential FDA approval of oxylanthanum carbonate (OLC) so we can bring this treatment to people with chronic kidney disease (CKD) on dialysis as efficiently as possible," said Shalabh Gupta, M.D., Chief Executive Officer of Unicycive. "The need for our differentiated treatment, which offers high potency and a significantly reduced pill burden for people struggling to control hyperphosphatemia, has been further validated by new patient survey findings and patient-reported outcomes data. We remain dedicated to bolstering our commercial infrastructure as we strive to deliver a much-needed solution to patients and healthcare providers."

Key Highlights & Upcoming Milestones

- The FDA has set a Prescription Drug User Fee Act (PDUFA) target action date of June 28, 2025, for OLC. Unicycive continues to prepare for the potential launch of OLC by building key functions, engaging directly with prescribers and other stakeholders, and supporting market access.

- Expanded awareness of OLC and its potential to address significant needs for CKD patients by publishing data and presentations at medical meetings.

    - Recently, findings were presented at the National Kidney Foundation (NKF) Spring Clinical Meetings and the 2025 American Nephrology Nurses Association (ANNA) National Symposium from a patient survey conducted in partnership with the NKF. The survey included a total of 200 dialysis patients who identified excessive pill numbers, large pill sizes, and forgetfulness as the primary barriers to phosphate binder adherence. Patients also expressed a strong preference for medication regimens with fewer and smaller pills.

    - New patient-reported outcomes data from the pivotal Phase 2 study of OLC were presented at the 2025 American Dialysis Conference (ADC) and the NKF Spring Clinical Meeting, which demonstrated that patients preferred OLC in comparison to their pre-trial phosphate binder medications and significantly enhanced patient satisfaction.

Financial Results for the Quarter Ended March 31, 2025

Research and Development (R&D) expenses were $2.2 million for the three months ended March 31, 2025, compared to $6.8 million for the three months ended March 31, 2024. The decrease in research and development expenses was primarily due to decreased drug development costs.

General and Administrative (G&A) expenses were $5.8 million for the three months ended March 31, 2025, compared to $2.4 million for the three months ended March 31, 2024. The increase was primarily due to increased consulting and professional services related to our commercial launch preparation.

In addition to the above launch expenses, we continue to focus on the manufacturing of commercial supplies, as reflected in prepaid expenses and other current assets on our balance sheet which increased from $4.8 million as of December 31, 2024 to $7.6 million as of March 31, 2025.

Other income was $8.6 million for the three months ended March 31, 2025, compared to an expense of $11.8 million for the three months ended March 31, 2024, primarily due to a decrease in the fair value of our warrant liability.

Net income attributable to common stockholders for the three months ended March 31, 2025, was $0.5 million, compared to a net loss attributable to common stockholders of $21.2 million for the three months ended March 31, 2024. The net income for the three-month period ended March 31, 2025, was primarily due to a decrease in the fair value of our warrant liability.

As of March 31, 2025, cash and cash equivalents totaled $19.8 million.

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 currently under review by the U.S. Food and Drug Administration (FDA) 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.

Unicycive Therapeutics, Inc.

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

	As of December 31, 2024	As of March 31, 2025 (Unaudited)
Assets		
Current assets:		
Cash	$ 26,142	$ 19,769
Prepaid expenses and other current assets	4,806	7,577
Total current assets	30,948	27,346
Right of use asset, net	645	518
Property, plant and equipment, net	75	83
Total assets	$ 31,668	$ 27,947
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,058	$ 1,397
Accrued liabilities	3,562	4,143
Warrant liability	18,936	10,588
Operating lease liability - current	564	548
Total current liabilities	24,120	16,676
Operating lease liability - long term	117	-
Total liabilities	24,237	16,676
Commitments and contingencies		
Stockholders' equity:		
Series A-2 Prime preferred stock, $0.001 par value per share - 21,338.01 Series A-2 Prime shares authorized at December 31, 2024 and March 31, 2025; 6,150.21 and 5,464.21 Series A-2 Prime shares issued and outstanding at December 31, 2024 and March 31, 2025, respectively	-	-
Series B-2 preferred stock, $0.001 par value per share - 7,882 Series B-2 shares authorized at December 31, 2024 and March 31, 2025; 3,000 Series B-2 shares issued and outstanding at December 31, 2024 and March 31, 2025	-	-
Preferred stock: $0.001 par value per share - 9,846,891 shares authorized at December 31, 2024 and March 31, 2025; zero shares issued and outstanding at December 31, 2024 and March 31, 2025	-	-
Common stock, $0.001 par value per share - 400,000,000 shares authorized at December 31, 2024 and March 31, 2025; 113,842,364 and 119,749,743 shares issued and outstanding at December 31, 2024 and March 31, 2025, respectively	114	120
Additional paid-in capital	108,587	111,851
Accumulated deficit	(101,270)	(100,700)
Total stockholders' equity	7,431	11,271
Total liabilities and stockholders' equity	$ 31,668	$ 27,947

Unicycive Therapeutics, Inc.

Statements of Operations

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

	Three Months Ended March 31,	
	2024	**2025**
Operating expenses:		
Research and development	$ 6,813	$ 2,171
General and administrative	2,391	5,818
Total operating expenses	9,204	7,989
Loss from operations	(9,204)	(7,989)
Other income (expenses):		
Interest income	69	226
Interest expense	(20)	(15)
Change in fair value of warrant liability	(11,808)	8,348
Total other income (expenses)	(11,759)	8,559
Net (loss) income	(20,963)	570
Net (loss) income attributable to common stockholders, basic	(21,171)	510
Net loss attributable to common stockholders, diluted	(21,171)	(6,214)
Net (loss) income per share:		
Basic	$ (0.61)	$ -
Diluted	$ (0.61)	$ (0.05)
Weighted-average shares outstanding:		
Basic	34,912,692	116,818,811
Diluted	34,912,692	123,834,773