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 12, 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.)

1975 W. El Camino Real, Suite 204
Mountain View, CA 94040
(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 May 12, 2026, Unicycive Therapeutics, Inc. issued a press release announcing its financial results for the first quarter ended March 31, 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 May 12, 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: May 12, 2026

UNICYCIVE THERAPEUTICS, INC.

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

Exhibit 99.1

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

- *U.S. Food and Drug Administration (FDA) review of oxylanthanum carbonate (OLC) New Drug Application (NDA) resubmission remains on track, with a Prescription Drug User Fee Act (PDUFA) target action date of June 29, 2026*

- *Commercial readiness activities continue in anticipation of the potential commercial launch of OLC*

MOUNTAIN VIEW, Calif., May 12, 2026 -- Unicycive Therapeutics, Inc. (Nasdaq: UNCY), a clinical-stage biotechnology company developing therapies for patients with kidney disease, today announced its financial results for the first quarter ended March 31, 2026, and provided a business update.

"As we approach the June 29th PDUFA target action date, we remain optimistic about the potential approval of OLC and focused on preparations for the subsequent launch of OLC," said Shalabh Gupta, M.D., Chief Executive Officer of Unicycive. "Our ongoing dialogue with the FDA during the review cycle has been constructive and timely. Uncontrolled hyperphosphatemia remains a significant health concern, affecting nearly 75% of U.S. patients with chronic kidney disease who are undergoing dialysis. OLC has the potential to improve adherence and phosphorus control with reduced pill burden, compared with currently available phosphate binders."

Key Highlights & Upcoming Milestones

- In January 2026, the Company announced the FDA accepted the resubmission of its NDA for OLC, an investigational oral phosphate binder for the treatment of hyperphosphatemia in patients with CKD on dialysis. The FDA set a PDUFA target action date of June 29, 2026. The NDA is supported by data from three clinical studies (a Phase 1 study in healthy volunteers, a bioequivalence study in healthy volunteers, and a tolerability study in patients with CKD on dialysis), multiple preclinical studies, and chemistry, manufacturing, and controls (CMC) data. The FDA did not raise any concerns regarding the preclinical, clinical, or safety data for OLC included in the original NDA submission. The December 2025 resubmission was based on progress made by the third-party manufacturing vendor responsible for the drug product.

- In preparation for a potential launch of OLC later this year, the Company continues to strengthen its commercial infrastructure and advance market readiness initiatives. Unicycive's goal is to optimize patient access across all reimbursement settings and intends to provide dedicated access and reimbursement support services for all patients through Unicycive's UniSource™ reimbursement hub.

Financial Results for the Quarter Ended March 31, 2026

As of May 11, 2026, unaudited cash, cash equivalents, and marketable securities totaled $57.1 million. The Company believes that it has sufficient resources to fund planned operations into 2027.

Research and Development (R&D) expenses were $1.6 million for the quarter ended March 31, 2026, compared to $2.2 million for the three months ended March 31, 2025. The decrease in research and development expenses was primarily attributed to a decrease in drug development costs as well as consulting and professional fees.

General and Administrative (G&A) expenses were $6.8 million for the quarter ended March 31, 2026, compared to $5.8 million for the three months ended March 31, 2025. The increase was primarily attributed to an increase in consulting, professional services, and labor costs.

Other income (expense) was $(4.4) million expense for the quarter ended March 31, 2026, compared to $8.6 million income for the three months ended March 31, 2025, attributed primarily to an increase in the fair value of the Company's warrant liability.

Net comprehensive income (loss) attributable to common stockholders, basic for the quarter ended March 31, 2026, was a $(12.8) million loss, or $(0.54) per share of common stock, compared to $0.5 million income, or $0.04 per share of common stock, for the three months ended March 31, 2025. Net comprehensive income (loss) attributable to common stockholders, diluted for the quarter ended March 31, 2026, was a $(12.8) million loss, or $(0.54) per share of common stock, compared to a $(6.2) million loss, or $(0.50) per share of common stock, for the three months ended March 31, 2025. The increased net loss for the quarter ended March 31, 2026, was attributed primarily to an increase in the fair value of the Company's warrant liability.

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, 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 March 31, 2026 (Unaudited)
Assets		
Current assets:		
Cash and cash equivalents	$ 29,198	$ 37,371
Prepaid expenses and other current assets	7,692	8,959
Marketable securities	12,071	17,215
Total current assets	48,961	63,545
Right of use asset, net	108	813
Property and equipment, net	66	48
Total Assets	$ 49,135	$ 64,406
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 383	$ 1,140
Accrued liabilities	1,523	3,052
Warrant liability	16,915	21,695
Operating lease liability – current	117	598
Total current liabilities	18,938	26,485
Operating lease liability – long term	—	217
Total Liabilities	18,938	26,702
Commitments and contingencies (Note 7)		
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 March 31, 2026; 2,265 Series A-2 Prime shares issued and outstanding at December 31, 2025, and March 31, 2026	—	—
Series B-2 preferred stock, $0.001 par value per share - 50,000 Series B-2 shares authorized at December 31, 2025, and March 31, 2026; zero Series B-2 shares issued and outstanding at December 31, 2025, and March 31, 2026	—	—
Preferred stock, $0.001 par value per share – 10,000,000 shares authorized at December 31, 2025, and March 31, 2026; zero shares issued and outstanding at December 31, 2025, and March 31, 2026	—	—
Common stock, $0.001 par value per share – 400,000,000 shares authorized at December 31, 2025, and March 31, 2026; 22,114,245 and 25,237,782 shares issued and outstanding at December 31, 2025, and March 31, 2026, respectively	22	25
Accumulated other comprehensive (loss) income	(1)	6
Additional paid-in capital	158,001	178,321
Accumulated deficit	(127,825)	(140,648)
Total Stockholders' Equity	30,197	37,704
Total Liabilities And Stockholders' Equity	$ 49,135	$ 64,406

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

	Three Months Ended March 31, 2025	Three Months Ended March 31, 2026
Operating expenses:		
Research and development	$ 2,171	$ 1,607
General and administrative	5,818	6,830
Total operating expenses	7,989	8,437
Loss from operations	(7,989)	(8,437)
Other income (expenses):		
Interest income	226	394
Interest expense	(15)	—
Change in fair value of warrant liability	8,348	(4,780)
Total other income (expenses)	8,559	(4,386)
Net income (loss)	570	(12,823)
Other comprehensive loss:		
Unrealized loss on marketable securities, net	—	(1)
Net comprehensive income (loss)	$ 570	$ (12,824)
Net comprehensive income (loss) attributable to common stockholders, basic	$ 510	$ (12,824)
Net comprehensive (loss) attributable to common stockholders, diluted	$ (6,214)	$ (12,824)
Net comprehensive income (loss) per share		
Basic	$ 0.04	$ (0.54)
Diluted	$ (0.50)	$ (0.54)
Weighted-average shares outstanding used in computing net comprehensive income (loss) per share:		
Basic	11,681,881	23,908,153
Diluted	12,383,477	23,908,153