

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): August 12, 2026

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

Delaware
(State or other jurisdiction
of incorporation or organization)

001-40582
(Commission File Number)

81-3638692
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 August 12, 2026, Unicycive Therapeutics, Inc. issued a press release announcing its financial results for the second quarter ended June 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 August 12, 2026.
104	Cover Page Interactive Data File (embedded within the 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: August 12, 2026

UNICYCIVE THERAPEUTICS, INC.

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



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

- Company expects to resubmit New Drug Application (NDA) for oxylanthanum carbonate (OLC) assuming completion of successful inspection of third-party manufacturing vendor

- FDA has assigned a facility inspection to third-party manufacturing vendor of OLC

- As of June 30, 2026, unaudited cash, cash equivalents, and marketable securities totaled \$61.4 million, with expected runway into 2027

MOUNTAIN VIEW, Calif., August 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 second quarter ended June 30, 2026, and provided a business update.

“We are focused on securing approval of oxylanthanum carbonate (OLC) and remain confident in the efficacy and safety of OLC and in its potential to improve care for patients with hyperphosphatemia on dialysis,” said Shalabh Gupta, M.D., Chief Executive Officer of Unicycive. “The latest update from our third-party manufacturing vendor is that the U.S. Food and Drug Administration (FDA) has assigned a facility inspection. This marks a positive step forward, and our dialogue with the FDA on OLC labeling and packaging has been productive and continuous throughout this process. We are optimistic about a successful inspection of the third-party manufacturing facility, which would enable us to promptly resubmit the NDA. In the meantime, we are well positioned to launch OLC as quickly as possible following potential approval, and we are utilizing this time to continue to expand market awareness in preparation for the commercial success of OLC.”

Key Highlights & Upcoming Milestones

- In June, the Company received a Complete Response Letter (CRL) from the FDA regarding the resubmitted NDA for OLC for the treatment of hyperphosphatemia in patients with chronic kidney disease on dialysis. The CRL cites the same third-party manufacturing deficiencies identified in a previous CRL issued in June 2025. The FDA has not raised any concerns regarding clinical efficacy or safety data, and no additional data was requested from the Company.
- The Company’s third-party vendor has received written notification from the FDA that the facility inspection has been assigned, and the Company plans to provide an update following completion of the FDA inspection.
- In preparation for the potential launch of OLC, the Company continues to advance its commercial readiness initiatives. Unicycive is focused on optimizing patient access across all reimbursement settings and plans to support patients with dedicated access and reimbursement services through its UniSource™ reimbursement hub.
- The Company will also engage with the patient and clinical community at several medical meetings during the third quarter, including the 51st Annual American Association of Kidney Patients National Patient Meeting (September 11–13, Little Rock, Arkansas) and the 2026 Renal Healthcare Association Annual Conference (September 23–26, Savannah, Georgia).

Financial Results for the Quarter Ended June 30, 2026

Research and Development (R&D) expense was \$2.8 million for the quarter ended June 30, 2026, compared to \$1.8 million for the three months ended June 30, 2025. The increase was primarily driven by a \$0.9 million increase in non-cash stock-based compensation, and an increase in consulting and professional fees of \$0.1 million.

General and Administrative (G&A) expense was \$7.4 million for the quarter ended June 30, 2026, compared to \$5.2 million for the three months ended June 30, 2025. The increase was primarily driven by a \$1.4 million increase in non-cash stock-based compensation as well as an increase of \$0.3 million in other labor costs. There was also an increase of \$0.4 million related to commercial launch preparation.

Other income (expense) was \$8.4 million for the quarter ended June 30, 2026, compared to \$0.5 million income for the three months ended June 30, 2025, attributed primarily to an increase in the fair value of the Company’s warrant liability.

Net loss attributable to common stockholders, basic and diluted, for the quarter ended June 30, 2026, was \$(1.7) million, or \$(0.06) per share of common stock, compared to \$(6.5) million loss, or \$(0.52) per share of common stock, for the three months ended June 30, 2025. The decreased net loss for the quarter ended June 30, 2026, was attributed primarily to a decrease 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 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](https://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

	As of December 31, 2025	As of June 30, 2026 (Unaudited)
Assets		
Current assets:		
Cash and cash equivalents	\$ 29,198	\$ 44,185
Prepaid expenses and other current assets	7,692	9,895
Marketable securities	12,071	17,240
Total current assets	48,961	71,320
Right of use asset, net	108	668
Property and equipment, net	66	41
Total assets	<u>\$ 49,135</u>	<u>\$ 72,029</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 383	\$ 2,234
Accrued liabilities	1,523	2,136
Warrant liability	16,915	13,718
Operating lease liability - current	117	616
Total current liabilities	18,938	18,704
Operating lease liability – long term	-	55
Total liabilities	18,938	18,759
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 June 30, 2026; 2,265 and zero Series A-2 Prime shares issued and outstanding at December 31, 2025, and June 30, 2026, respectively	-	-
Series B-2 preferred stock, \$0.001 par value per share – 50,000 Series B-2 shares authorized at December 31, 2025, and June 30, 2026; zero Series B-2 shares issued and outstanding at December 31, 2025, and June 30, 2026	-	-
Preferred stock, \$0.001 par value per share – 10,000,000 shares authorized at December 31, 2025, and June 30, 2026; zero shares issued and outstanding at December 31, 2025, and June 30, 2026	-	-
Common stock, \$0.001 par value per share – 400,000,000 shares authorized at December 31, 2025, and June 30, 2026; 22,114,245 and 27,855,257 shares issued and outstanding at December 31, 2025, and June 30, 2026, respectively	22	28
Accumulated other comprehensive loss	(1)	(23)
Additional paid-in capital	158,001	195,635
Accumulated deficit	(127,825)	(142,370)
Total stockholders' equity	30,197	53,270
Total liabilities and stockholders' equity	<u>\$ 49,135</u>	<u>\$ 72,029</u>

	Three Months Ended June 30,	
	2025	2026
Operating expenses:		
Research and development	1,750	2,788
General and administrative	5,213	7,352
Total operating expenses	6,963	10,140
Loss from operations	(6,963)	(10,140)
Other income (expenses):		
Interest income	155	441
Interest expense	(13)	-
Change in fair value of warrant liability	374	7,977
Total other income (expenses)	516	8,418
Net loss	(6,447)	(1,722)
Other comprehensive loss:		
Unrealized loss on marketable securities, net	-	(29)
Net comprehensive loss	\$ (6,447)	\$ (1,751)
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.52)	\$ (0.06)
Weighted-average shares outstanding used in computing net loss per share	12,302,059	26,917,266