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 14, 2024**

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 August 14, 2024, Unicycive Therapeutics, Inc. issued a press release announcing its financial results for the three months ended June 30, 2024 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 14, 2024.
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 14, 2024

UNICYCIVE THERAPEUTICS, INC.

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

Unicycive Announces Second Quarter 2024 Financial Results and Provides Business Update

– On Track to Submit OLC New Drug Application (NDA) by End of August 2024 –

LOS ALTOS, Calif., August 14, 2024 – Unicycive Therapeutics, Inc. (Nasdaq: UNCY) (the "Company" or "Unicycive"), a clinical-stage biotechnology company developing therapies for patients with kidney disease, today announced its financial results for the three months ended June 30, 2024, and provided a business update.

"Achieving successful results from our oxylanthanum carbonate (OLC) pivotal trial was a significant milestone for the company and brings us one step closer to becoming a commercial organization," said Shalabh Gupta, M.D., Chief Executive Officer of Unicycive. "Importantly, the trial confirmed tolerability of OLC in patients with hyperphosphatemia on dialysis which is the final data component needed to support submission of a New Drug Application (NDA) to the FDA utilizing the 505(b)(2) regulatory pathway. In addition, we were able to achieve phosphate control in 90% of patients at the end of their titration. Our recent pharmacokinetic analysis of samples from the pivotal study revealed that the systemic exposure of our drug is minimal and, as expected, the serum lanthanum levels are similar to that seen with Fosrenol®. With this data, we believe that we have completed all the necessary requirements from this pivotal clinical trial to fulfill the FDA's requests. We remain on track to submit our NDA by the end of August 2024 and we maintain a high degree of confidence in the potential for OLC to be a best-in-class commercial product, if approved."

"In July 2024 we were granted a new patent for UNI-494 by the USPTO which is an important component of our development strategy to target patients with acute kidney injury (AKI), a serious condition resulting from a sudden loss of kidney function. We have completed enrollment in the UNI-494 Phase 1 dose-ranging study and expect to report results in the third quarter of this year. With assets targeting both chronic and acute kidney conditions, we remain steadfastly focused on improving treatment options and overall quality of life for patients living with renal diseases," concluded Dr. Gupta.

Key Highlights

- Reported positive topline data from the pivotal clinical trial of OLC with regard to both safety and tolerability endpoints. The study established promising tolerability of OLC at clinically effective doses in chronic kidney disease (CKD) patients on hemodialysis. In terms of tolerability, OLC had a low rate of discontinuation due to adverse events (AEs) with only 5/86 patients (6%) discontinuing from the Study. The primary endpoint was defined as the rate of discontinuations due to treatment-related AEs leading to discontinuation in the maintenance period. In the UNI-OLC-201 trial, the discontinuation rate was 1.4%, as there was only 1 discontinuation due to a treatment-related AE in the Evaluable Population (n=71). In the full Safety Population (n=86), a total of 3 patients discontinued due to treatment-related AEs, a rate of 3.5%. There were no treatment-related serious adverse events (SAEs).

- Announced initial results from the patient reported outcome survey conducted during the UNI-OLC-201 pivotal clinical trial. In the survey, OLC consistently outperformed the other phosphate binders in all categories: 79% of patients preferred OLC while 18% preferred their prior therapy, 98% of patients said that OLC was easy to take compared to 55% for their prior therapy, 89% of patients said they were satisfied with OLC while 49% were satisfied with their prior therapy.

- Enrollment in the UNI-494 Phase 1 study is complete, and the Company expects to present the data in Q3 2024.

- Granted a patent on UNI-494 to treat AKI by the United States Patent and Trademark Office (USPTO). The patent, valid until 2040, secures protection of a method of treating a disease or a condition selected from AKI or contrast induced nephropathy by administering the UNI-494 compound.

- Included in the Russell Microcap® Index effective July 1, 2024. Membership in the Russell Microcap® Index, which remains in place for one year, means automatic inclusion in the appropriate growth and value style indexes.

- Delivered multiple presentations on OLC and UNI-494 at the 61st European Renal Association (ERA) Congress including two oral presentations and trial-in-progress posters on OLC and UNI-494. An oral presentation demonstrated a significant reduction in urinary phosphate excretion for OLC compared to vehicle treated animals. A second oral presentation evaluated the *in vivo* efficacy of UNI-494 and showed that a single oral dose of UNI-494 significantly reduced important kidney functional markers.

- Presented two posters related to OLC at the National Kidney Foundation (NKF) Spring Clinical Meeting. Importantly, it was demonstrated that OLC is bioequivalent to lanthanum carbonate from the Phase 1, single-center, randomized 1:1, open-label, controlled, 2-way crossover study. In addition, a poster presentation on the findings of a survey of 100 renal dieticians concluded that strategies that reduce pill burden and increase ease of use for patients are needed. This poster was among the top-rated submissions to the Meeting.

Financial Results for the Quarter Ended June 30, 2024

Research and Development (R&D) expenses were $4.9 million for the three months ended June 30, 2024, compared to $2.3 million for the three months ended June 30, 2023. The increase in research and development expenses was primarily due to increased drug development costs.

General and Administrative (G&A) expenses were $2.5 million for the three months ended June 30, 2024, compared to $2.1 million for the three months ended June 30, 2023. The increase was primarily due to increased non-cash stock compensation costs.

Other Income (Expense) was $17.3 million for the three months ended June 30, 2024 compared to $0.5 million in the three months ended June 30, 2023, due primarily to a decrease in the fair value of our warrant liability.

Net income attributable to common stockholders for the three months ended June 30, 2024 was $3.0 million, and basic earnings per share was $0.08. On a diluted basis, we

reported a loss per share for the same period of $0.15. The net income for the three-month period ended June 30, 2024 was attributable to a decrease in the fair value of our warrant liability. For the three months ended June 30, 2023, we reported a net loss of $4.4 million, and basic loss per share of $0.29. On a diluted basis, we reported a loss per share for the same period of $0.29.

As of June 30, 2024, cash and cash equivalents totaled $41.8 million. The Company believes that it has sufficient resources to fund planned operations into 2026.

About Unicycive Therapeutics

Unicycive Therapeutics is a biotechnology company developing novel treatments for kidney diseases. Unicycive's lead drug candidate, oxylanthanum carbonate (OLC), is a novel investigational phosphate binding agent being developed for the treatment of hyperphosphatemia in chronic kidney disease patients on dialysis. UNI-494 is a patent-protected new chemical entity in clinical development for the treatment of conditions related to acute kidney injury. For more information, please visit Unicycive.com and follow us on LinkedIn and YouTube.

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; 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, 2023, 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.

Fosrenol® is a registered trademark of Shire International Licensing BV.

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SOURCE: Unicycive Therapeutics, Inc.

--Tables to Follow--

Unicycive Therapeutics, Inc.

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

	As of December 31, 2023	As of June 30, 2024 (Unaudited)
Assets		
Current assets:		
Cash and cash equivalents	$ 9,701	$ 41,780
Prepaid expenses and other current assets	3,698	2,274
Total current assets	13,399	44,054
Right of use asset, net	766	604
Property, plant and equipment, net	26	43
Total assets	$ 14,191	$ 44,701
Liabilities, mezzanine equity, and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 839	$ 1,472
Accrued liabilities	3,234	3,122
Dividends payable	-	1
Warrant liability	13,134	8,131
Operating lease liability - current	327	360
Total current liabilities	17,534	13,086
Operating lease liability – long term	466	274
Total liabilities	18,000	13,360
Commitments and contingencies (Note 8)		
Mezzanine equity:		
Series B-1 preferred stock, $0.001 par value per share – zero shares authorized at December 31, 2023, and 50,000 shares authorized at June 30, 2024; zero shares outstanding at December 31, 2023, and 50,000 shares outstanding at June 30, 2024	-	46,187
Stockholders' deficit:		

Series A-2 preferred stock, $0.001 par value per share – 43,649 Series A-2 shares authorized at December 31, 2023 and 21,388.01 Series A-2 Prime shares authorized at June 30, 2024; 43,649 Series A-2 shares outstanding at December 31, 2023 and 17,073.07 Series A-2 Prime shares outstanding at June 30, 2024	-	-
Preferred stock: $0.001 par value per share—9,926,161 and 9,904,773 shares authorized at December 31, 2023 and June 30, 2024, respectively; zero shares issued and outstanding at December 31, 2023 and June 30, 2024	-	-
Common stock, $0.001 par value per share – 200,000,000 shares authorized at December 31, 2023 and 400,000,000 shares authorized at June 30, 2024; 34,756,049 and 43,573,212 shares issued and outstanding at December 31, 2023 and June 30, 2024, respectively	35	43
Additional paid-in capital	60,697	60,760
Accumulated deficit	(64,541)	(75,649)
Total stockholders' deficit	(3,809)	(14,846)
Total liabilities and stockholders' deficit	$ 14,191	$ 44,701

Unicycive Therapeutics, Inc.

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

	Three Months Ended June 30,	
	2023	**2024**
Operating expenses:		
Research and development	$ 2,267	$ 4,868
General and administrative	2,055	2,533
Total operating expenses	4,322	7,401
Loss from operations	(4,322)	(7,401)
Other income (expenses):		
Interest income	234	462
Interest expense	(32)	(16)
Change in fair value of warrant liability	282	16,810
Total other income (expenses)	484	17,256
Net income (loss)	(3,838)	9,855
Deemed dividend to Series A-1 preferred stockholders	(603)	-
Dividend to Series B-1 preferred stockholders	-	(887)
Net income attributable to participating securities	-	(5,925)
Net income (loss) attributable to common stockholders	$ (4,441)	$ 3,043
Net income (loss) per share attributable to common stockholders, basic	$ (0.29)	$ 0.08
Net loss per share attributable to common stockholders, diluted	$ (0.29)	$ (0.15)
Weighted-average shares outstanding used in computing net income (loss) per share, basic	15,234,570	37,914,812
Weighted-average shares outstanding used in computing net loss per share, diluted	15,234,570	94,052,853