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 13, 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 May 13, 2024, Unicycive Therapeutics, Inc. issued a press release announcing its financial results for the three months ended March 31, 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 May 13, 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: May 13, 2024

UNICYCIVE THERAPEUTICS, INC.

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

Unicycive Announces First Quarter 2024 Financial Results and Provides Business Update

– On Track to Provide Topline Data from the Ongoing Pivotal Clinical Trial with Oxylanthanum Carbonate (OLC) in Q2 2024 –

– Multiple Presentations on OLC and UNI-494 at Prominent, Upcoming Medical Meetings –

LOS ALTOS, Calif., May 13, 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 March 31, 2024, and provided a business update.

"This is an exciting time for Unicycive as we progress towards the conclusion of our pivotal clinical trial for our lead asset oxylanthanum carbonate (OLC)," said Shalabh Gupta, M.D., Chief Executive Officer of Unicycive. "The trial is evaluating the tolerability, safety, and pharmacokinetics of clinically effective doses of OLC in patients with chronic kidney disease (CKD) on dialysis and it remains on track with topline data expected later this quarter. If approved, OLC may provide a meaningful improvement in the quality of life for CKD patients on dialysis with hyperphosphatemia by reducing the pill burden volume by more than 4-fold compared to the most prescribed phosphate binder[1]."

Dr. Gupta, continued, "We are also developing UNI-494 for the prevention of delayed graft function (DGF) after kidney transplantation and other conditions related to acute kidney injury. This is an important indication as DGF is one of the most serious complications resulting from kidney transplantation. UNI-494 is advancing through the multiple ascending dose (MAD) portion of its Phase 1 study, and we expect to complete the trial and report the full results in the second half of this year."

"A priority for us in 2024 is expanding awareness of our programs within the medical and scientific communities. This month we will be presenting important data on both OLC and UNI-494 at two of the most prominent, global nephrology meetings hosted by the National Kidney Foundation and the European Renal Association. We look forward to providing updates on our programs at these events for all of our stakeholders," concluded Dr. Gupta.

Key Highlights

- Topline data expected in the second quarter of 2024 from the pivotal clinical trial of OLC in chronic kidney disease (CKD) patients on dialysis with hyperphosphatemia.
- Multiple presentations related to OLC and UNI-494 will be presented at the National Kidney Foundation (NKF) Spring Clinical Meeting (May 14-18) and the 61st European Renal Association (ERA) Congress (May 23-26). Among these presentations, a poster titled "Renal Dietitians Perceive Phosphate Binder and Low Phosphorus Diet Non-Compliance as Top Reasons for Above Target Serum Phosphorus Concentrations", by lead author Kathleen M. Hill Gallant from the University of Minnesota-Twin Cities was among the top-rated submissions to the NKF Spring Clinical Meeting. The poster reports on the findings from a survey of 100 renal dietitians on factors contributing to patient non-compliance to phosphate binder therapy and the most appealing features of Oxylanthanum Carbonate, if approved.

- Completed enrollment in the open-label, single-arm, multicenter, multidose pivotal clinical trial with OLC, a next-generation lanthanum-based phosphate binding agent utilizing proprietary nanoparticle technology being developed to treat hyperphosphatemia in patients with CKD on dialysis.
- Granted orphan drug designation (ODD) by the FDA to UNI-494 for the prevention of DGF in kidney transplant patients. ODD may provide certain tax credits for qualified clinical trials, exemption of user fees, and the potential for seven years of market exclusivity after approval. UNI-494 is a cytoprotective agent that elicits an ischemic preconditioning effect by activating K_{ATP} channels in mitochondria to restore cellular function.
- Presented new data demonstrating statistically significant results for UNI-494 in a preclinical model of DGF at the 29th International Conference on Advances in Critical Care Nephrology AKI and CRRT 2024. The data provides additional evidence that UNI-494 may be a valuable asset for prevention of DGF and other conditions related to acute kidney injury.
- Successfully completed the single ascending dose (SAD) portion of the Company's ongoing Phase 1 clinical trial in UNI-494. UNI-494 was well-tolerated up to 160 mg administered as a single dose and was chosen as the go-forward dose based on promising safety, tolerability, and pharmacokinetic data. In the multiple ascending dose (MAD) portion of the study, 80 mg is now being administered twice-a-day to trial participants.
- Completed a private placement with new and existing healthcare institutional investors that generated $50 million in gross proceeds to Unicycive.

Financial Results for the Quarter Ended March 31, 2024

Licensing Revenues: There were no licensing revenues recorded for the quarter ended March 31, 2024. Licensing revenues of approximately $0.7 million were recorded in the three months ended March 31, 2023, due to an upfront payment for a licensing agreement entered into with Lotus International PTE Ltd.

Research and development (R&D) Expenses: R&D expenses were $6.8 million for the three months ended March 31, 2024, compared to $3.0 million for the three months ended March 31, 2023. The increase in research and development expenses was primarily due to one time costs related to the OLC clinical trial.

General and Administrative (G&A) Expenses: G&A expenses were $2.4 million for the three months ended March 31, 2024, compared to $1.8 million for the three months ended March 31, 2023. The increase in general and administrative expenses was primarily due to an increase in non-cash stock compensation costs.

Other Income (Expenses): Other income (expenses) was $11.8 million for the three months ended March 31, 2024, compared to $10.4 million for the three months ended March 31, 2023. The increase was due primarily to a $11.8 million change in fair value of our warrant liability.

Net Loss: Net loss attributable to common stockholders for the three months ended March 31, 2024 was $21.2 million, or $0.61 per share of common stock, compared to a net loss of $14.8 million, or $0.97 per share of common stock, for the three months ended March 31, 2023. This increase was attributable primarily to increased drug development costs and the change in fair value of our warrant liability.

Cash Position: As of March 31, 2024, cash and cash equivalents totaled $48.9 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.

1 **Sprague, et al, "High Phosphate-Binding Capacity of Oxylanthanum Carbonate with a Low Medication Volume: Comparison with Commercially Available Phosphate Binders",** ***American Journal of Nephrology, September 2023***

Investor Contact:

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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 March 31, 2024 (Unaudited)
Assets		
Current assets:		
Cash and cash equivalents	$ 9,701	$ 48,930
Prepaid expenses and other current assets	3,698	2,746
Total current assets	13,399	51,676
Right of use asset, net	766	686
Property, plant and equipment, net	26	23
Total assets	$ 14,191	$ 52,385
Liabilities, mezzanine equity, and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 839	$ 1,240
Accrued liabilities	3,234	3,550
Dividends Payable	-	208
Warrant liability	13,134	24,941
Operating lease liability - current	327	343
Total current liabilities	17,534	30,282
Operating lease liability – long term	466	372
Total liabilities	18,000	30,654
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 March 31, 2024; zero shares outstanding at December 31, 2023, and 50,000 shares outstanding at March 31, 2024		46,187
Stockholders' deficit:		

Series A-2 Prime preferred stock, $0.001 par value per share – 43,649 shares authorized at December 31, 2023, and 21,388 shares authorized at March 31, 2024; 43,649 shares outstanding at December 31, 2023, and 19,992 shares outstanding at March 31, 2024	-	-
Preferred stock: $0.001 par value per share—9xxxxxx shares authorized at December 31, 2023, and March 31, 2024, respectively; zero shares issued and outstanding at December 31, 2023, and March 31, 2024	-	-
Common stock, $0.001 par value per share – 200,000,000 shares authorized at December 31, 2023, and March 31, 2024; 34,756,049 shares issued and outstanding at December 31, 2023, and 37,606,630 shares issued and outstanding at March 31, 2024	35	37
Additional paid-in capital	60,697	61,011
Accumulated deficit	(64,541)	(85,504)
Total stockholders' deficit	(3,809)	(24,456)
Total liabilities and stockholders' deficit	$ 14,191	$ 52,385

Unicycive Therapeutics, Inc.

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

	Three Months Ended March 31,	
	2023	**2024**
Licensing revenues:	$ 675	$ -
Operating expenses:		
Research and development	3,030	6,813
General and administrative	1,847	2,391
Total operating expenses	4,877	9,204
Loss from operations	(4,202)	(9,204)
Other income (expenses):		
Interest income	14	69
Interest expense	(12)	(20)
Change in fair value of warrant liability	(10,375)	(11,808)
Total other income (expenses)	(10,373)	(11,759)
Net loss	(14,575)	(20,963)
Deemed dividend to Series A-1 preferred stockholders	(192)	-
Dividend to Series B preferred stockholders	-	(208)
Net loss attributable to common stockholders	$ (14,767)	$ (21,171)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.97)	$ (0.61)
Weighted-average shares outstanding used in computing net loss per share, basic and diluted	15,232,406	34,912,692