

**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): **November 13, 2024**

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

UNICYCIVE THERAPEUTICS, INC.

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



Unicycive Announces Third Quarter 2024 Financial Results and Provides Business Update

– OLC New Drug Application (NDA) Accepted by the FDA with a PDUFA Target Action Date of June 28, 2025 –

– Commercial Planning in Progress for 2025 Launch –

– Late Breaker Poster Presentation on OLC at ASN Kidney Week –

– Successful Completion of UNI-494 Phase 1 Trial –

LOS ALTOS, Calif., November 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 September 30, 2024, and provided a business update.

“We are pleased with the tremendous progress we have made over the last several months highlighted by the acceptance of our New Drug Application for oxylanthanum carbonate (OLC) which may result in the potential approval of our first drug in 2025,” said Shalabh Gupta, M.D., Chief Executive Officer of Unicycive. “If approved, we believe OLC’s high potency and low pill burden would provide a best-in-class option for patients with chronic kidney disease (CKD) on dialysis who have hyperphosphatemia and face adherence challenges with current treatment regimens. With the NDA acceptance now behind us, we are actively preparing to commercialize OLC with the goal of bringing this innovative new treatment to market in the second half of 2025.”

“We have also made progress on our second asset, UNI-494, as we announced the successful completion of our Phase 1 clinical trial providing the necessary data to potentially advance to Phase 2 clinical development. UNI-494 is targeting acute kidney injury (AKI), a challenging and often under-treated disease. We plan to request a meeting with the FDA by the end of this year to continue advancing our clinical development program for UNI-494,” concluded Dr. Gupta.

Key Highlights

- Announced the acceptance of the New Drug Application (NDA) by the U.S. Food and Drug Administration (FDA) for OLC for the treatment of hyperphosphatemia in patients with CKD on dialysis. The FDA set a Prescription Drug User Fee Act (PDUFA) Target Action Date of June 28, 2025.
 - 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 compared to 18% of patients who preferred their prior therapy; 98% of patients said that OLC was easy to take compared to 55% for their prior therapy; and 89% of patients said they were satisfied with OLC while only 49% were satisfied with their prior therapy.
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- Announced the successful completion of the UNI-494 Phase 1 study in healthy volunteers. The Phase 1 study was a single center, double-blind, placebo-controlled, randomized single ascending dose (Part 1) and multiple ascending dose (Part 2) study in healthy volunteers conducted in the United Kingdom. UNI-494 was well-tolerated as a single dose up to 160 mg and in multiple doses at 40 mg twice-a-day. The absorption of UNI-494 was fast, and UNI-494 was rapidly metabolized to release nicorandil. Collectively, the results will help determine the dose and schedule of UNI-494 in a potential Phase 2 clinical trial in patients with acute kidney injury.
 - 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 (“method of use”) related to AKI or contrast-induced-nephropathy by administering the UNI-494 compound.
 - Delivered four presentations on OLC and UNI-494 at the American Society of Nephrology (ASN) Kidney Week 2024 including a late-breaker poster presentation highlighting favorable safety and tolerability data of OLC. The presentation highlighted the positive pivotal clinical trial data demonstrating that OLC was able to achieve serum phosphate control in more than 90% of patients with CKD on dialysis who entered the maintenance phase of the trial. A poster presentation also described the results from the UNI-494 Phase 1 study results, and two preclinical posters were presented.
 - Two preclinical studies for both OLC and UNI-494 were featured in two publications: “Systemic Absorption of Oxylanthanum Carbonate is Minimal in Preclinical Models” was published in the *Pharmaceutical Chemistry Journal*; “Evaluation of UNI-494 in Acute Kidney Injury Treatment Efficacy When Administered After Ischemia-Reperfusion in a Rat Model” was published in *EC Pharmacology and Toxicology*.
 - UNCY was added to the Russell Microcap[®] Index effective July 1, 2024. Membership in the Russell Microcap[®] Index, which remains in place for one year is accompanied by automatic inclusion in the appropriate growth and value style indexes.

Financial Results for the Quarter Ended September 30, 2024

Research and Development (R&D) expenses were \$3.0 million for the three months ended September 30, 2024, compared to \$3.4 million for the three months ended September 30, 2023. The decrease in research and development expenses was primarily due to decreased drug development costs.

General and Administrative (G&A) expenses were \$3.2 million for the three months ended September 30, 2024, compared to \$2.6 million for the three months ended September 30, 2023. The increase was primarily due to increased non-cash stock compensation expense.

Other Income was \$2.2 million for the three months ended September 30, 2024 compared to \$1.6 million in the three months ended September 30, 2023, due primarily to a decrease in the fair value of our warrant liability.

Net loss attributable to common stockholders for the three months ended September 30, 2024 was \$4.1 million, compared to a net loss attributable to common stockholders of \$4.4 million, for the three months ended September 30, 2023. The decreased net loss for the three-month period ended September 30, 2024 was attributable to a decrease in the fair value of our warrant liability.

As of September 30, 2024, cash and cash equivalents totaled \$32.3 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. Positive pivotal trial results were reported in June 2024 for OLC. The Company has submitted a New Drug Application for OLC with the U.S. Food and Drug Administration and the FDA set a Prescription Drug User Fee Act (PDUFA) Target Action Date of June 28, 2025.

OLC is protected by a strong global patent portfolio including issued patent on composition of matter with exclusivity until 2031, and with the potential patent term extension until 2035 after OLC approval.

UNI-494 is a patent-protected new chemical entity in clinical development for the treatment of conditions related to acute kidney injury. UNI-494 has successfully completed a Phase 1 trial. 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.

Investor Contact:

Kevin Gardner
LifeSci Advisors
kgardner@lifesciadvisors.com

Chris Calabrese
LifeSci Advisors
ccalabrese@lifesciadvisors.com

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 September 30, 2024 (Unaudited)
Assets		
Current assets:		
Cash and cash equivalents	\$ 9,701	\$ 32,347
Prepaid expenses and other current assets	3,698	5,394
Total current assets	13,399	37,741
Right of use asset, net	766	772
Property, plant and equipment, net	26	61
Total assets	\$ 14,191	\$ 38,574
Liabilities and stockholders' (deficit) equity		
Current liabilities:		
Accounts payable	\$ 839	\$ 548
Accrued liabilities	3,234	2,992
Warrant liability	13,134	6,377
Operating lease liability - current	327	542
Total current liabilities	17,534	10,459
Operating lease liability – long term	466	265
Total liabilities	18,000	10,724
Commitments and contingencies		
Stockholders' (deficit) equity:		

Series A-2 Prime 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 September 30, 2024; 43,649 Series A-2 shares outstanding at December 31, 2023 and 11,111.24 Series A-2 Prime shares outstanding at September 30, 2024	-	-
Series B-2 preferred stock, \$0.001 par value per share – zero Series B-2 shares authorized at December 31, 2023 and 7,882 Series B-2 Prime shares authorized at September 30, 2024; zero Series B-2 shares outstanding at December 31, 2023 and 7,882 Series B-2 shares outstanding at September 30, 2024	-	-
Preferred stock: \$0.001 par value per share—10,000,000 shares authorized at December 31, 2023 and September 30, 2024; zero shares issued and outstanding at December 31, 2023 and September 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 September 30, 2024; 34,756,049 and 97,858,406 shares issued and outstanding at December 31, 2023 and September 30, 2024, respectively	35	98
Additional paid-in capital	60,697	107,497
Accumulated deficit	(64,541)	(79,745)
Total stockholders' (deficit) equity	(3,809)	27,850
Total liabilities and stockholders' (deficit) equity	\$ 14,191	\$ 38,574

4

Unicyclic Therapeutics, Inc.

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

	Three Months Ended September 30,	
	2023	2024
Operating expenses:		
Research and development	\$ 3,372	\$ 3,045
General and administrative	2,566	3,206
Total operating expenses	5,938	6,251
Loss from operations	(5,938)	(6,251)
Other income (expenses):		
Interest income	227	416
Interest expense	(18)	(15)
Change in fair value of warrant liability	1,396	1,754
Total other income (expenses)	1,605	2,155
Net loss	(4,333)	(4,096)
Deemed dividends to Series A-1 preferred stockholders	(72)	-
Net loss attributable to common stockholders	\$ (4,405)	\$ (4,096)
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.13)	\$ (0.05)
Weighted-average shares outstanding used in computing net loss per share, basic and diluted	32,633,074	88,943,212

5