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): **March 31, 2025**

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 March 31, 2025, Unicycive Therapeutics, Inc. issued a press release announcing its financial results for the full year ended December 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 March 31, 2025.
104	Cover Page Interactive Data File (embedded within 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: March 31, 2025

UNICYCIVE THERAPEUTICS, INC.

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

Exhibit 99.1

Unicycive Therapeutics Announces Full Year 2024 Financial Results and Provides Business Update

- Oxylanthanum carbonate (OLC) New Drug Application for hyperphosphatemia in chronic kidney disease patients on dialysis under review by the FDA with a PDUFA target action date of June 28, 2025

- Commercial Planning in Preparation for anticipated commercial launch of OLC in late 2025

LOS ALTOS, California, March 31, 2025 -- Unicycive Therapeutics, Inc. (Nasdaq: UNCY), a clinical-stage biotechnology company developing therapies for patients with kidney disease, today announced its financial results for the full year ended December 31, 2024, and provided a business update.

"2025 is positioned to be a transformational year for Unicycive, with the near-term potential for FDA approval and commercial launch of oxylanthanum carbonate (OLC)," said Shalabh Gupta, M.D., Chief Executive Officer of Unicycive. "For approximately 75% of people in the U.S. with chronic kidney disease (CKD) on dialysis, hyperphosphatemia remains uncontrolled because of challenges with currently available phosphate binders, potentially increasing their risk of hospitalization and mortality. If approved, we believe OLC is positioned to be an important new option for these patients, distinguished by its high potency and a low pill burden. We continue to actively prepare to launch OLC, including educating key stakeholders on existing OLC data and preparing our commercial infrastructure to rapidly make OLC available to patients upon approval."

Key Highlights & Upcoming Milestones

- 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.

- Unicycive's partner in the Republic of Korea, Lotus Pharmaceutical, submitted an NDA for OLC with the Ministry of Food and Drug Safety and anticipates an application decision in June of 2026. Unicycive has an exclusive license agreement with Lotus Pharmaceutical for the development, registration, and commercialization of OLC in the Republic of Korea and has the potential to receive up to $3.7 million in milestone payments and tiered royalties based on regulatory and commercial achievements.

- Continued efforts to establish an efficient commercial infrastructure, including building key functions, engaging directly with prescribers and other stakeholders and preparing to support market access are ongoing.

- Expanded awareness of OLC and its potential to address significant needs for CKD patients through publication of data, including in the peer-reviewed journals *Clinical Therapeutics, Clinical and Translational Science,* and *Journal of Nephrological Science;* and late-breaker presentation at the American Society of Nephrology (ASN) Kidney Week 2024. This included clinical, preclinical and patient survey/literature review data that highlighted OLC's favorable safety and tolerability profile, efficacy in controlling serum phosphate levels, and the need for new options to overcome the current limitations of phosphate binders and their effects on patients' quality of life. The data also demonstrated OLC's bioequivalence to approved lanthanum carbonate chewable tablets, and the potential benefits of combination treatment of OLC and tenapanor on phosphate management.

- Successfully completed Phase 1 study of UNI-494 in healthy volunteers, which demonstrated favorable tolerability, with fast absorption and rapid metabolization. Data from the Phase 1 study and supportive preclinical data were presented at ASN 2024 and published in *EC Pharmacology and Toxicology*.

Financial Results for the Year Ended December 31, 2024

Licensing revenues decreased approximately $0.7 million, from the year ended December 31, 2023 due to an upfront payment of approximately $0.7 million associated with a licensing agreement entered into with Lotus International Pte Ltd. in February 2023. There was no comparable revenue earned in the current period.

Research and Development (R&D) expenses were $20.0 million for the year ended December 31, 2024, compared to $12.9 million for the same period in 2023. The increase in research and development expenses was primarily due to an increase in drug development and labor costs.

General and Administrative (G&A) expenses were $12.1 million for the year ended December 31, 2024, compared to $8.5 million for the same period in 2023. The increase was primarily due to an increase in labor, consulting and professional services costs.

Other Income was $4.6 million for the year ended December 31, 2024 compared to $9.8 million in the same period in 2023 due primarily to a decrease in the fair value of our warrant liability.

Net loss attributable to common stockholders for the year ended December 31, 2024 was $37.8 million, or $0.56 per share of common stock, compared to a net loss attributable to common stockholders of $31.4 million, or $1.28 per share of common stock for the same period in 2023. The increased net loss for the year ended December 31, 2024 was attributable primarily to an increase in drug development costs.

As of December 31, 2024, cash and cash equivalents totaled $26.1 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, and a New Drug Application (NDA) is under review by the U.S. Food and Drug Administration (FDA) with a Prescription Drug User Fee Act (PDUFA) Target Action Date of June 28, 2025. OLC is protected by a strong global patent portfolio including an issued patent on composition of matter with exclusivity until 2031, and with the potential patent term extension until 2035 after OLC approval. Unicycive's second asset, 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, X, 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; 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, 2024, 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 Contacts:

Kevin Gardner
LifeSci Advisors
kgardner@lifesciadvisors.com

Media Contact:

Rachel Visi
Real Chemistry
redery@realchemistry.com

SOURCE: Unicycive Therapeutics, Inc.

Unicycive Therapeutics, Inc.
Balance Sheets
(in thousands, except for share and per share amounts)

	As of December 31, 2023	As of December 31, 2024
Assets		
Current assets:		
Cash	$ 9,701	$ 26,142
Prepaid expenses and other current assets	3,698	4,806
Total current assets	13,399	30,948
Right of use asset, net	766	645
Property, plant and equipment, net	26	75
Total assets	$ 14,191	$ 31,668
Liabilities and stockholders' (deficit) equity		
Current liabilities:		
Accounts payable	$ 839	$ 1,058
Accrued liabilities	3,234	3,562
Warrant liability	13,134	18,936
Operating lease liability - current	327	564
Total current liabilities	17,534	24,120
Operating lease liability - long term	466	117
Total liabilities	18,000	24,237
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 December 31, 2024; 43,649 Series A-2 shares outstanding at December 31, 2023 and 6,150.21 Series A-2 Prime shares outstanding at December 31, 2024	-	-
Series B-2 preferred stock, $0.001 par value per share – zero and 7,882 shares authorized at December 31, 2023 and December 31, 2024, respectively; zero and 3,000 shares outstanding at December 31, 2023 and December 31, 2024, respectively	-	-
Preferred stock: $0.001 par value per share—9,926,161 and 9,846,891 shares authorized at December 31, 2023 and December 31, 2024, respectively; zero shares issued and outstanding at December 31, 2023 and December 31, 2024	-	-
Common stock, $0.001 par value per share – 200,000,000 shares and 400,000,000 shares authorized at December 31, 2023 and December 31, 2024, respectively; 34,756,049 shares issued and outstanding at December 31, 2023, and 113,842,364 shares issued and outstanding at December 31, 2024	35	114
Additional paid-in capital	60,697	108,587
Accumulated deficit	(64,541)	(101,270)
Total stockholders' (deficit) equity	(3,809)	7,431
Total liabilities and stockholders' (deficit) equity	$ 14,191	$ 31,668

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

	Year Ended December 31, 2023	Year Ended December 31, 2024
Licensing revenues	$ 675	$ -
Operating expenses:		
Research and development	12,902	20,014
General and administrative	8,547	12,103
Total operating expenses	21,449	32,117
Loss from operations	(20,774)	(32,117)
Other income (expenses):		
Interest income	615	1,261
Interest expense	(82)	(71)
Change in fair value of warrant liability	(10,303)	(5,802)
Total other income (expenses)	(9,770)	(4,612)
Net loss	(30,544)	(36,729)
Deemed dividends to Series A-1 preferred stockholders	(867)	-
Dividends to Series B-1 preferred stockholders	-	(1,095)
Net loss attributable to common stockholders	$ (31,411)	$ (37,824)
Net loss per share attributable to common stockholders, basic and diluted	$ (1.28)	$ (0.56)
Weighted-average shares outstanding used in computing net loss per share, basic and diluted	24,539,309	66,985,129