

**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 11, 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 8.01 Other Events.

On November 11, 2024, Unicycive Therapeutics, Inc. issued a press release announcing that the U.S. Food and Drug Administration has accepted the New Drug Application for Oxylanthanum Carbonate (OLC) and has set a Prescription Drug User Fee Act (PDUFA) target action date of June 28, 2025. A copy of the press release is furnished as Exhibit 99.1 to this Form 8-K.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits.

| | |
|------|--|
| 99.1 | Press Release of Unicycive Therapeutics, Inc. dated November 11, 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 12, 2024

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



Unicycive Therapeutics Announces U.S. FDA Acceptance of the New Drug Application (NDA) for Oxylanthanum Carbonate (OLC) for the Treatment of Hyperphosphatemia in Patients with Chronic Kidney Disease on Dialysis

– FDA sets PDUFA Action Date of June 28, 2025

– Company Preparing for 2025 Commercial Launch –

LOS ALTOS, California, November 11, 2024 -- Unicycive Therapeutics, Inc. (Nasdaq: UNCY), a clinical-stage biotechnology company developing therapies for patients with kidney disease (the “Company” or “Unicycive”), today announced that the U.S. Food and Drug Administration (FDA) has accepted the New Drug Application (NDA) for Oxylanthanum Carbonate (OLC) and has set a Prescription Drug User Fee Act (PDUFA) target action date of June 28, 2025. If approved, OLC has the potential to meaningfully improve the treatment burden for hyperphosphatemia patients with chronic kidney disease (CKD) on dialysis.

“We are thrilled with the FDA acceptance of our first NDA, a significant milestone towards our efforts to bring this important treatment option to patients with kidney disease if approved,” said Shalabh Gupta, MD, Chief Executive Officer of Unicycive. “CKD patients on dialysis with hyperphosphatemia are often saddled with an onerous treatment regimen that includes having to take as many as 12 pills per day. OLC may have meaningful patient adherence benefits over currently available treatment options as it requires a lower pill burden for patients in terms of the number and size of pills per dose, and the pills are swallowed instead of chewed for added convenience. With our NDA now under review, we are preparing to commercialize and launch OLC in the second half of 2025, if approved.”

Unicycive is seeking FDA approval of OLC via the 505(b)(2) regulatory pathway. The NDA submission package is based on data from three clinical studies (a Phase 1 study in healthy volunteers, a bioequivalence study in healthy volunteers, and a tolerability study of OLC in CKD patients on dialysis), multiple preclinical studies, and the chemistry, manufacturing and controls (CMC) data. OLC is protected by a strong global patent portfolio including issued patents on composition of matter with exclusivity until 2031, and with the potential for patent term extension until 2035

As previously announced, the FDA granted a waiver for the NDA application PDUFA fees, representing a significant savings of approximately \$4 million for Unicycive.

About Oxylanthanum Carbonate (OLC)

Oxylanthanum carbonate is a next-generation lanthanum-based phosphate binding agent utilizing proprietary nanoparticle technology being developed for the treatment of hyperphosphatemia in patients with chronic kidney disease (CKD) on dialysis. OLC has over thirty issued and granted patents globally. Its potential best-in-class profile may have meaningful patient adherence benefits over currently available treatment options as it requires a lower pill burden for patients in terms of number and size of pills per dose that are swallowed instead of chewed. Based on a survey conducted in 2022, Nephrologists stated that the greatest unmet need in the treatment of hyperphosphatemia with phosphate binders is a lower pill burden and better patient compliance.¹ The global market opportunity for treating hyperphosphatemia is expected to exceed \$2.5 billion, with the United States accounting for more than \$1 billion of that total². Despite the availability of several FDA-cleared medications, 75 percent of U.S. dialysis patients fail to achieve the target phosphorus levels recommended by published medical guidelines.

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

About Hyperphosphatemia

Hyperphosphatemia is a serious medical condition that occurs in nearly all patients with End Stage Renal Disease (ESRD). If left untreated, hyperphosphatemia leads to secondary hyperparathyroidism (SHPT), which then results in renal osteodystrophy (a condition similar to osteoporosis and associated with significant bone disease, fractures and bone pain); cardiovascular disease with associated hardening of arteries and atherosclerosis (due to deposition of excess calcium-phosphorus complexes in soft tissue). Importantly, hyperphosphatemia is independently associated with increased mortality for patients with chronic kidney disease on dialysis. Based on available clinical data to date, over 80% of patients show signs of cardiovascular calcification by the time they become dependent on dialysis.

Dialysis patients are already at an increased risk for cardiovascular disease (because of underlying diseases such as diabetes and hypertension), and hyperphosphatemia further exacerbates this. Treatment of hyperphosphatemia is aimed at lowering serum phosphate levels via two means: (1) restricting dietary phosphorus intake; and (2) using, on a daily basis, and with each meal, oral phosphate binding drugs that facilitate fecal elimination of dietary phosphate rather than its absorption from the gastrointestinal tract into the bloodstream.

¹ Reason Research, LLC 2022 survey. Results here.

² Fortune Business Insights[™], *Hyperphosphatemia Treatment Market, 2021-2028*

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](https://www.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; 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.

FOR MORE INFORMATION, PLEASE CONTACT:

Investors:

Kevin Gardner

LifeSci Advisors
kgardner@lifesciadvisors.com

Chris Calabrese

LifeSci Advisors
ccalabrese@lifesciadvisors.com

SOURCE: Unicycive Therapeutics, Inc.