

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): September 28, 2026

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.)

1975 W. El Camino Real, Suite 204
Mountain View, CA 94040
(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 5.02 Departure of Directors or Principal Officers; Election of Directors; Appointment of Principal Officers.

On September 28, 2026, Unicycive Therapeutics, Inc. (the “Company”) appointed Meredith S. Manning as an independent director on the Company’s board of directors, effective October 1, 2026. Ms. Manning will serve on each of the Audit, Compensation and Nominating and Corporate Governance Committees, and also as the Chairperson of the Nominating and Corporate Governance Committee.

Meredith S. Manning, M.B.A., has more than 25 years of global biopharmaceutical experience. Most recently, she served as Chief Commercial Officer of Soleno Therapeutics, Inc. from 2024 until its acquisition by Neurocrine Biosciences, Inc. in 2026. At Soleno, she built the commercial organization from inception and led the U.S. launch of VYKAT™ XR, the first FDA-approved treatment for hyperphagia in Prader-Willi syndrome. As a member of the executive team, she also played a key role in asset evaluation, lifecycle planning, and due diligence, and led the selection of ex-U.S. distribution partners. Previously, Ms. Manning served as President, The Americas, and a voting member of the U.S. Board of Directors of PharmaEssentia Corporation from 2020 to 2023. In this role, she built the U.S. company from the ground up, with general management and P&L responsibility for all U.S. functions. She was a key member of the team that secured FDA approval of BESREMi® (ropeginterferon alfa-2b-njft), led its U.S. commercial launch, and supported the company’s capital-raising efforts, including engagement with U.S. and global investors. Prior to joining PharmaEssentia, she served as Chief Commercial Officer of resTORbio, Inc. Earlier in her career, Ms. Manning served as Vice President, Global Marketing and Product Strategy Lead, Hemophilia, at Shire (formerly Baxter/Baxalta), where she led a seven-brand portfolio across more than 65 countries. She also held senior U.S. marketing and field leadership roles at Vertex Pharmaceuticals Incorporated, including the launch of INCIVEK® (telaprevir), and director-level roles in oncology business development, marketing, and managed care at Pfizer Inc. Ms. Manning holds a B.A. in political science from The Colorado College and an M.B.A. from the University of Chicago Booth School of Business.

The Company believes that Ms. Manning is qualified to serve on its Board of Directors because of her extensive experience building and leading biopharmaceutical organizations, her record of successful product launches across rare disease, oncology, and hematology, and her general management, global commercialization, and value-creation expertise.

There is no arrangement or understanding between Ms. Manning and any other person, other than the Company’s directors acting solely in their capacity as such, pursuant to which she was selected as a director of the Company. Ms. Manning is not related by blood, marriage or adoption to any director or executive officer.

The Company is not aware of any transaction, or currently proposed transaction, in which the Company was or is to be a participant and in which Ms. Manning, or any member of her immediate family, had or will have a direct or indirect material interest that would be required to be reported under Item 404(a) of Regulation S-K.

Item 8.01 Other Events.

On September 29, 2026, the Company issued a press release announcing resubmission of a New Drug Application for Oxylanthanum Carbonate. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and incorporated by reference herein (except for the fourth paragraph therein).

Item 9.01. Financial Statements and Exhibits

(d) Exhibits.

99.1	Press Release of Unicycive Therapeutics, Inc. dated September 29, 2026.
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: September 29, 2026

UNICYCIVE THERAPEUTICS, INC.

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



Unicycive Therapeutics Announces Resubmission of New Drug Application for Oxylanthanum Carbonate

- *Resubmission of NDA includes Chemistry, Manufacturing, and Controls (CMC) data from a new drug product manufacturing vendor*
- *The resubmission package includes 12 months of OLC drug product stability data from the new manufacturing vendor*
- *Company anticipates FDA acceptance of the NDA within 30 days of resubmission; new assigned PDUFA date expected to be 6 months from resubmission*
- *Current cash position allows runway into 2H 2027*

MOUNTAIN VIEW, Calif., September 29, 2026 -- Unicycive Therapeutics, Inc. ("Unicycive" or the "Company") (Nasdaq: UNCY), a clinical-stage biotechnology company developing therapies for patients with kidney disease, today announced the resubmission of its New Drug Application (NDA) for oxylanthanum carbonate (OLC), the Company's investigational oral phosphate binder for the treatment of hyperphosphatemia in patients with chronic kidney disease (CKD) on dialysis. The Company anticipates United States Food and Drug Administration (FDA) acceptance of the NDA within 30 days and a new assigned PDUFA date to be six months from the date of resubmission.

The NDA resubmission includes CMC data from a new third-party drug product manufacturing vendor. The new vendor's facility was last inspected by the FDA in March 2024 and received "No Action Indicated" status, the highest FDA inspection classification indicating that a facility is in an acceptable state of current Good Manufacturing Practices (cGMP) compliance. The new vendor's CMC data package includes technical specifications similar to the original third-party manufacturing vendor, and the new vendor has already produced OLC drug product and completed 12-month stability studies. In addition, the Company has provided additional in-vitro bridging data between the two vendors as recommended by the FDA in previous discussions.

In June 2026, the Company received a Complete Response Letter (CRL) from the FDA regarding the first OLC NDA resubmission. The 2026 CRL cited the same third-party manufacturing deficiencies identified in a previous CRL issued in June 2025 to the initial NDA submission, as a result of the FDA not having conducted the reinspection of the original third-party manufacturing vendor. The FDA did not raise concerns regarding clinical efficacy or safety data and did not request additional data from the Company. The Company's original third-party manufacturing vendor has received written notification from the FDA that its facility inspection has been assigned, but the inspection has not yet occurred as of September 29, 2026. If the original third-party manufacturing vendor is inspected in the near term and deemed cGMP-compliant, the Company plans to seek FDA alignment on a shorter approval timeline for the OLC NDA resubmission. Unicycive intends to keep both drug product vendors to maintain supply chain redundancy.

“We believe this resubmission reflects an efficient path to potential approval and, if approved, a potentially faster path to bringing OLC to patients who need additional treatment options,” said Shalabh Gupta, M.D., Chief Executive Officer of Unicycive. “By adding an alternative primary manufacturing vendor, we are positioning the NDA for expedient review and potential approval. If the FDA’s assigned inspection of the original vendor is completed favorably in the interim, that outcome could provide a potential timing benefit. We continue to advance commercial readiness activities in anticipation of a potential launch, with the goal of helping patients with CKD on dialysis who continue to struggle with hyperphosphatemia.”

The NDA is supported by 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, along with multiple preclinical studies and CMC data.

As of June 30, 2026, unaudited cash, cash equivalents and marketable securities totaled \$61.4 million, supporting continued OLC commercial launch preparation and an expected cash runway into the second half of 2027.

About Oxylanthanum Carbonate

OLC is an investigational oral phosphate binder that leverages proprietary nanoparticle technology to deliver high phosphate binding potency, reducing the number and size of pills that patients must take to treat hyperphosphatemia in patients with chronic kidney disease (CKD) on dialysis. Its potential best-in-class profile may have meaningful patient adherence benefits over currently available treatment options as it requires a lower pill burden.

Unicycive is seeking FDA approval of OLC via the 505(b)(2) regulatory pathway. 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.

About Hyperphosphatemia

Hyperphosphatemia is a serious medical condition that occurs in nearly all patients with End Stage Renal Disease (ESRD). Annually there are over 450,000 individuals in the U.S. that require medication to control their phosphate levels.¹ Uncontrolled hyperphosphatemia is strongly associated with increased death and hospitalization for CKD patients on dialysis. 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 Flythe JE. Dialysis-Past, Present, and Future: A Kidney360 Perspectives Series. *Kidney360*. 2023 May 1;4(5):567-568. doi: 10.34067/KID.0000000000000145.

About Unicycive Therapeutics

Unicycive Therapeutics is a biotechnology company developing novel treatments for kidney diseases. Unicycive's lead investigational treatment is oxylanthanum carbonate, a novel phosphate binding agent for the treatment of hyperphosphatemia in patients with chronic kidney disease who are on dialysis. Unicycive's second investigational treatment UNI-494 is intended for the treatment of conditions related to acute kidney injury. It has been granted orphan drug designation (ODD) by the FDA for the prevention of Delayed Graft Function (DGF) in kidney transplant patients and has completed a Phase 1 dose-ranging safety study in healthy volunteers. For more information, please visit Unicycive.com and follow us on LinkedIn and X.

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; the possibility that FDA may require inspection of any vendor prior to approval, which could delay or prevent approval of our NDA; the risk that the original third-party manufacturing vendor's reinspection may not occur within a timeframe that benefits our regulatory timeline, or may result in adverse findings; 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, 2025, 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.

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SOURCE: Unicycive Therapeutics, Inc.