UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

Individually and on Behalf of All Others Similarly Situated, Plaintiff, v. UNICYCIVE THERAPEUTICS, INC., SHALABH GUPTA, AND JOHN TOWNSEND, Defendants.	Case No. **CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS**

Plaintiff ("Plaintiff"), individually and on behalf of all others similarly situated, by and through his attorneys, alleges the following upon information and belief, except as to those allegations concerning Plaintiff, which are alleged upon personal knowledge. Plaintiff's information and belief is based upon, among other things, his counsel's investigation, which includes without limitation: (a) review and analysis of regulatory filings made by Unicycive Therapeutics, Inc. ("Unicycive" or the "Company") with the United States ("U.S.") Securities and Exchange Commission ("SEC"); (b) review and analysis of press releases and media reports issued by and disseminated by Unicycive; and (c) review of other publicly available information concerning Unicycive.

NATURE OF THE ACTION AND OVERVIEW

1. This is a class action on behalf of persons and entities that purchased or otherwise acquired Unicycive securities between December 29, 2025 and June 29, 2026, inclusive (the "Class Period"). Plaintiff pursues claims against the Defendants under the Securities Exchange Act of 1934 (the "Exchange Act").

2. Unicycive is a clinical-stage biotechnology company, identifies, develops, and commercializes therapies for the treatment of kidney diseases.

3. Unicycive submitted a New Drug Application ("NDA") for its kidney disease therapy, oxylanthanum carbonate ("OLC"), to the U.S. Food and Drug Administration ("FDA") in September 2024. The NDA was accepted by the FDA in November 2024. In June 2025, the FDA issued a Complete Response Letter ("CRL") citing deficiencies at a third-party manufacturing vendor. Following the CRL, Unicycive held a Type A meeting with the FDA in October 2025 to discuss the single deficiency related to the third-party manufacturing vendor's compliance status. After receiving official meeting minutes and engaging with the vendor, Unicycive resubmitted the NDA in December 2025.

4. On June 30, 2026, before the market opened, Unicycive disclosed that the FDA had issued a CRL regarding the Company's resubmitted NDA for OLC, identifying the "***same third-party manufacturing deficiencies that were identified in the previous CRL issued in June 2025***."[1]

5. On this news, Unicycive's stock price fell $3.01, or 39.1%, to close at $4.69 per share on June 30, 2026, on unusually heavy trading volume.

6. Throughout the Class Period, Defendants made materially false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operations, and prospects. Specifically, Defendants failed to disclose to investors: (1) that the Company had not inspected its third-party manufacturing vendor's facility or otherwise audited the facility's compliance with current good manufacturing practices; (2) that, as a result, the Company lacked a reasonable basis to believe that the vendor had resolved the FDA's cited deficiencies; (3) that there was an undisclosed risk that the FDA would require additional information about the vendor's facility's manufacturing practices; (4) that, as a result of the foregoing, the regulatory approval of OLC was reasonably likely to be delayed; and (5) that, as a result of the foregoing, Defendants' positive statements about the Company's business, operations, and prospects were materially misleading and/or lacked a reasonable basis.

7. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

JURISDICTION AND VENUE

8. The claims asserted herein arise under Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)), as amended by the Private Securities Litigation Reform Act of 1995, and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

9. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and Section 27 of the Exchange Act (15 U.S.C. § 78aa).

[1] Unless otherwise stated, all emphasis in bold and italics hereinafter is added.

10. Venue is proper in this Judicial District pursuant to 28 U.S.C. § 1391(b) and Section 27 of the Exchange Act (15 U.S.C. § 78aa). Substantial acts in furtherance of the alleged fraud or the effects of the fraud have occurred in this Judicial District. Many of the acts charged herein, including the dissemination of materially false and/or misleading information, occurred in substantial part in this Judicial District. In addition, the Company's principal executive offices are located in this District.

11. In connection with the acts, transactions, and conduct alleged herein, Defendants directly and indirectly used the means and instrumentalities of interstate commerce, including the United States mail, interstate telephone communications, and the facilities of a national securities exchange.

PARTIES

12. Plaintiff as set forth in the accompanying certification, incorporated by reference herein, purchased Unicycive securities during the Class Period, and suffered damages as a result of the federal securities law violations and false and/or misleading statements and/or material omissions alleged herein.

13. Defendant Unicycive is incorporated under the laws of Delaware with its principal executive offices located in Mountain View, California. Unicycive's common stock trades on the NASDAQ exchange under the symbol "UNCY."

14. Defendant Shalabh Gupta ("Gupta") was the Company's Chief Executive Officer ("CEO") at all relevant times.

15. Defendant John Townsend ("Townsend") was the Company's Chief Financial Officer ("CFO") at all relevant times.

16. Defendants Gupta and Townsend (collectively the "Individual Defendants"), because of their positions with the Company, possessed the power and authority to control the contents of the Company's reports to the SEC, press releases and presentations to securities analysts, money and portfolio managers and institutional investors, i.e., the market. The Individual Defendants were provided with copies of the Company's reports and press releases alleged herein

to be misleading prior to, or shortly after, their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material non-public information available to them, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to, and were being concealed from, the public, and that the positive representations which were being made were then materially false and/or misleading. The Individual Defendants are liable for the false statements pleaded herein.

SUBSTANTIVE ALLEGATIONS

Background

17. Unicycive is a clinical-stage biotechnology company, identifies, develops, and commercializes therapies for the treatment of kidney diseases.

18. Unicycive submitted an NDA, for its kidney disease therapy, oxylanthanum carbonate or OLC, to the FDA in September 2024. The NDA was accepted by the FDA in November 2024.

19. In June 2025, the FDA issued a CRL for the OLC NDA. The FDA's only stated concern related to a third-party manufacturing vendor's failure to adhere to current good manufacturing practices ("cGMP"). In the press release announcing the CRL, Unicycive acknowledged that these deficiencies were "previously identified" at that vendor but were "unrelated to Oxylanthanum Carbonate (OLC)." Further, Unicycive claimed that it had already identified "a back-up third party manufacturing vendor" that "has already produced OLC drug product, which could also be used to support the resolution of the CMC [Clinical Manufacturing and Controls] issues identified in the CRL."

20. Following the CRL, Unicycive held a Type A meeting with the FDA in fall 2025 to discuss the single deficiency related to the third-party manufacturing vendor's compliance status. After receiving official meeting minutes and engaging with the vendor, Unicycive resubmitted the NDA in December 2025.

Materially False and Misleading

Statements Issued During the Class Period

21. The Class Period begins on December 29, 2025. On that day, Unicycive announced "it has resubmitted its 505(b)(2) New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for oxylanthanum carbonate (OLC)." The press release touted, among other things, that the Company's ***"original third-party manufacturing vendor has made significant progress toward regaining FDA compliance, allowing us to resubmit the OLC NDA as planned."*** Specifically, the press release stated as follows, in relevant part:

> LOS ALTOS, Calif., Dec. 29, 2025 (GLOBE NEWSWIRE) -- Unicycive Therapeutics, Inc. ("Unicycive" or the "Company") (Nasdaq: UNCY), a clinical-stage biotechnology company developing therapies for patients with kidney disease, today announced that it has resubmitted its 505(b)(2) New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) 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.
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> ***"Our original third-party manufacturing vendor has made significant progress toward regaining FDA compliance, allowing us to resubmit the OLC NDA as planned,"*** said Shalabh Gupta, M.D., Chief Executive Officer of Unicycive. "With a cash runway into 2027, we are well-positioned to complete the regulatory approval process for OLC so we can prepare to bring this important treatment option to dialysis patients with hyperphosphatemia as soon as possible."
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> ***The NDA for OLC was resubmitted based on continued progress by the original third-party manufacturing vendor in resolving FDA-cited deficiencies and demonstrating inspection readiness.*** Unicycive previously discussed these milestones during a Type A meeting with the FDA in September 2025, which was held to obtain feedback and alignment on resolving the single deficiency identified in the Company's Complete Response Letter (CRL) related to the compliance status of the vendor. No additional issues were raised by the FDA.

22. On January 29, 2026, the Company announced "the U.S. Food and Drug Administration (FDA) has accepted the resubmission of its New Drug Application (NDA) for oxylanthanum carbonate (OLC)." The press release touted, among other things, that the "NDA is supported by data from three clinical studies . . . multiple preclinical studies as well as chemistry, manufacturing and controls (CMC) data." Specifically, the press release stated as follows, in relevant part:

> **Unicycive Therapeutics Announces FDA Acceptance of Oxylanthanum Carbonate (OLC) New Drug Application (NDA) Resubmission**

FDA assigns Prescription Drug User Fee Act (PDUFA) target date of June 29, 2026

Ended 2025 with unaudited cash position of $41.3M with expected runway into 2027

LOS ALTOS, Calif., Jan. 29, 2026 (GLOBE NEWSWIRE) -- Unicycive Therapeutics, Inc. ("Unicycive" or the "Company") (Nasdaq: UNCY), a clinical-stage biotechnology company developing therapies for patients with kidney disease, today announced that the U.S. Food and Drug Administration (FDA) has accepted 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 Agency has deemed the OLC resubmission to be a Class II complete response which has a six-month review period from the date of resubmission and set a Prescription Drug User Fee Act (PDUFA) target action date of June 29, 2026.

"We are pleased that the agency has promptly accepted the resubmission of our NDA for OLC," said Shalabh Gupta, M.D., Chief Executive Officer of Unicycive. "We are advancing our commercial preparation activities in anticipation of a potential launch of OLC later this year, to help provide an important treatment option to patients with chronic kidney disease (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), multiple preclinical studies as well as chemistry, manufacturing and controls (CMC) data. The FDA did not raise any concerns regarding OLC's preclinical, clinical, or safety data included in the original NDA submission.

The Company ended 2025 with an unaudited position of $41.3 million in cash, cash equivalents, and short-term investments, which permits continued advancement of OLC commercial launch activities and a cash runway into 2027.

23. On March 30, 2026, the Company issued a press release announcing its financial results for the full year ended December 31, 2025 and provided a business update. The press release touted the Company's submission of the NDA for OLC, including that "***[t]he resubmission in December 2025 was based on the progress made by the third-party manufacturing vendor responsible for the drug product (Drug Product).***" Specifically, the press release stated as follows, in relevant part:

Key Highlights & Upcoming Milestones

● In January 2026, the Company announced the FDA has accepted the resubmission of its NDA for OLC, an investigational oral phosphate binder for the treatment of hyperphosphatemia in patients with CKD on dialysis. The FDA set a PDUFA target action date of June 29, 2026. 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 in patients with CKD on dialysis), multiple preclinical studies and chemistry, manufacturing and controls (CMC) data. The FDA

did not raise any concerns regarding the preclinical, clinical or safety data for OLC included in the original NDA submission. ***The resubmission in December 2025 was based on the progress made by the third-party manufacturing vendor responsible for the drug product (Drug Product).***

● As part of Unicycive's continued preparation to support a potential launch of OLC later this year, the Company is continuing to strengthen its commercial infrastructure and advance market readiness initiatives.

24. On March 30, 2026, the Company submitted its annual report for the fiscal year ended December 31, 2025 on a Form 10-K filed with the SEC (the "FY25 10-K"). The FY25 10-K affirmed the previously reported financial results. The FY25 10-K further touted the Company's progress with its CRL for OLC, including that the Company had discussed the "***resolution of the single deficiency identified in the CRL related to the compliance status of a third-party manufacturing vendor.***" Specifically, the FY25 10-K stated as follows, in relevant part:

> We are seeking the U.S. Food and Drug Administration (FDA) approval of OLC via the 505(b)(2) regulatory pathway. In September 2024, we submitted a New Drug Application (NDA) for OLC to the FDA. In November 2024 we announced the FDA had accepted its NDA and set a Prescription Drug User Fee Act (PDUFA) target action date of June 28, 2025. In June 2025, the FDA issued us a Complete Response Letter (CRL) notifying us that a third-party manufacturing vendor of its main contract development and manufacturing organization (CDMO) was cited for deficiencies following a cGMP inspection. No other concerns have been identified to us, including pre-clinical, clinical, or safety data submitted as part of the NDA. I***n October 2025, we held a Type A meeting with the FDA to discuss the resolution of the single deficiency identified in the CRL related to the compliance status of a third-party manufacturing vendor. Following receipt of the official meeting minutes from the Type A meeting and engaging in discussions with its third-party manufacturing vendor, we resubmitted its NDA to the FDA in December 2025. In January 2026, the FDA accepted the resubmission of the NDA for OLC, deeming the resubmission to be a Class II complete response which has a six-month review period from the date of resubmission, and set a PDUFA) target action date of June 29, 2026.***

25. The FY25 10-K further purported to warn of risks which "***could***" or "***may***" negatively impact the Company, including those related to regulatory approval of its current product candidates. Specifically, the FY25 10-K stated as follows, in relevant part:

> Obtaining clearances or approvals from the FDA and from the regulatory agencies in other countries is an expensive and time-consuming process and is uncertain as to outcome. The FDA and other agencies could ask us to supplement our submissions, collect new CMC or non-clinical data, conduct additional clinical trials or engage in other time-consuming actions, or it could simply deny our applications. In addition, even if we obtain an NDA approval or pre-market approvals in other countries, the approval could be revoked, or other restrictions imposed if post-market data

demonstrate safety issues or lack of effectiveness. ***In response to our initial NDA submission, the FDA issued a CRL notifying us that a third-party manufacturing vendor of its main contract development and manufacturing organization (CDMO) was cited for deficiencies following a cGMP inspection. We resubmitted an NDA in December 2025 and the FDA set a PDUFA target action date of June 29, 2026. If the third party fails inspection again or if the NDA is rejected again, we will need to make another NDA submission and our target PDUFA target action date will be extended by another 6-12 months.*** We cannot predict with certainty how, or when, the FDA or other regulatory agencies will act. If we are unable to obtain the necessary regulatory approvals, our financial condition and cash flow may be adversely affected, and our ability to grow domestically and internationally may be limited. Additionally, even if cleared or approved, our products may not be approved for the specific indications that are most necessary or desirable for successful commercialization or profitability.

26. The FY25 10-K purported to warn that the third-parties could fail to fulfill their obligations to the Company, stating in relevant part:

Our reliance on third parties heightens the risks faced by our business.

We rely on suppliers, vendors and partners for certain key aspects of our business, including support for information technology systems and certain human resource functions. We do not control these partners, but we depend on them in ways that may be significant to us. ***For example, our third-party manufacturing vendor of its main contract development and manufacturing organization (CDMO) was cited for deficiencies following a cGMP inspection resulting in the FDA issuing us a CRL for our initial NDA submission which resulted in us having to resubmit an NDA causing delay in our target action PFUDA date of 12-months. If these parties fail to meet our expectations or fulfill their obligations to us, we may fail to receive the expected benefits.*** In addition, if any of these third parties fails to comply with applicable laws and regulations in the course of its performance of services for us, there is a risk that we may be held responsible for such violations as well.

27. The FY25 10-K purported to warn that "if" the Company experienced issues with its third party vendors, it "could delay clinical development or marketing approval." Specifically, the Company stated in relevant part:

We have no experience manufacturing product candidates on a clinical or commercial scale and will be dependent on third parties for the manufacture of our product candidates. If we experience problems with any of these third parties or their subcontractors or vendors, they could delay clinical development or marketing approval of our product candidates or our ability to sell any approved products.

We do not have any manufacturing facilities. We expect to rely on third-party manufacturers for the manufacture of our product candidates for clinical trials and for commercial supply of any product candidate for which we obtain marketing approval.

We may be unable to establish agreements with third-party manufacturers for clinical or commercial supply on terms favorable to us, or at all. ***Even if we are able to***

establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- ***reliance on the third party for regulatory compliance and quality assurance;***

- the possible breach of the manufacturing agreement by the third party, including the inability to supply sufficient quantities or to meet quality standards or timelines; and

- the possible termination or non-renewal of the agreement by the third party at a time that is costly or inconvenient for us.

Third-party manufacturers may not be able to comply with U.S. cGMPs or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, or their subcontractors, to comply with cGMPs or other applicable regulations, even if such failures do not relate specifically to our product candidates or approved products, could result in sanctions being imposed on us or the manufacturers, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates, operating restrictions and criminal prosecutions, any of which could adversely affect supplies of our product candidates and harm our business and results of operations. ***For example, our third-party manufacturing vendor of its main contract development and manufacturing organization (CDMO) was cited for deficiencies following a cGMP inspection resulting in the FDA issuing us a CRL for our initial NDA submission which resulted in us having to resubmit an NDA causing delay in our target action PFUDA date of 12-months.***

Any product that we develop may compete with other product candidates and products for access to these manufacturing facilities. There are a limited number of manufacturers that operate under cGMPs and that might be capable of manufacturing for us.

Any performance failure on the part of our manufacturers, including a failure that may not relate specifically to our product candidates or approved products, could delay clinical development or marketing approval or adversely impact our ability to generate commercial sales. If our contract manufacturers cannot perform as agreed, we may be required to replace that manufacturer.

Our anticipated future dependence upon others for the manufacture and supply of our current and future product candidates or products may adversely affect our future profit margins and our ability to commercialize any product candidates that receive marketing approval on a timely and competitive basis.

Furthermore, we expect to rely on third parties to release, label, store and distribute drug supplies for our clinical trials. Any performance failure on the part of these third parties, including a failure that may not relate specifically to our product candidates, could delay or otherwise adversely impact clinical development or marketing approval of our product candidates or commercialization of our drug, producing losses and depriving us of potential revenue. ***Our supplier Shilpa Medicare Ltd was reviewed by the FDA in March 2025.***

Moreover, our manufacturers and suppliers may experience difficulties related to their overall businesses and financial stability, which could result in delays or interruptions of supply of our product candidates.

28. On May 12, 2026, Unicycive issued a press release announcing its financial results for the first quarter ended March 31, 2026 and provided a business update. Specifically, the press release stated as follows, in relevant part:

> **Unicycive Therapeutics Announces First Quarter 2026 Financial Results and Provides Business Update**
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> ***U.S. Food and Drug Administration (FDA) review of oxylanthanum carbonate (OLC) New Drug Application (NDA) resubmission remains on track, with a Prescription Drug User Fee Act (PDUFA) target action date of June 29, 2026***
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> *Commercial readiness activities continue in anticipation of the potential commercial launch of OLC*
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> **MOUNTAIN VIEW, Calif., May 12, 2026 --** Unicycive Therapeutics, Inc. (Nasdaq: UNCY), a clinical-stage biotechnology company developing therapies for patients with kidney disease, today announced its financial results for the first quarter ended March 31, 2026, and provided a business update.
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> "As we approach the June 29th PDUFA target action date, we remain optimistic about the potential approval of OLC and focused on preparations for the subsequent launch of OLC," said Shalabh Gupta, M.D., Chief Executive Officer of Unicycive. ***"Our ongoing dialogue with the FDA during the review cycle has been constructive and timely.*** Uncontrolled hyperphosphatemia remains a significant health concern, affecting nearly 75% of U.S. patients with chronic kidney disease who are undergoing dialysis. OLC has the potential to improve adherence and phosphorus control with reduced pill burden, compared with currently available phosphate binders."
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> **Key Highlights & Upcoming Milestones**
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> ● In January 2026, the Company announced the FDA accepted the resubmission of its NDA for OLC, an investigational oral phosphate binder for the treatment of hyperphosphatemia in patients with CKD on dialysis. The FDA set a PDUFA target action date of June 29, 2026. 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 in patients with CKD on dialysis), multiple preclinical studies, and chemistry, manufacturing, and controls (CMC) data. The FDA did not raise any concerns regarding the preclinical, clinical, or safety data for OLC included in the original NDA submission. ***The December 2025 resubmission was based on progress made by the third-party manufacturing vendor responsible for the drug product.***

29. On May 12, 2026, the Company submitted its quarterly report for the period ended March 31, 2026 on a Form 10-Q filed with the SEC, affirming the previously reported financial results. The report touted the Company's progress with its CRL for OLC, including that the Company had discussed the ***"resolution of the single deficiency identified in the CRL related to***

the compliance status of a third-party manufacturing vendor." Specifically, the quarterly report stated as follows, in relevant part:

> On October 28, 2025,we announced an update from our meeting with the U.S. Food and Drug Administration (FDA) and timing of the resubmission of our New Drug Application (NDA) for Oxylanthanum carbonate (OLC) following receipt of a CRL on June 30, 2025. The Type A FDA meeting was held to discuss the r***esolution of the single deficiency identified in the CRL related to the compliance status of a third-party manufacturing vendor. No other concerns have been identified to us, including pre-clinical, clinical, or safety data submitted as part of the NDA. Following receipt of the official meeting minutes from the Type A meeting and engaging in discussions with our third-party manufacturing vendor, we resubmitted our NDA to the FDA in December 2025.*** In January 2026, the FDA accepted the resubmission of the NDA for OLC, deeming the resubmission to be a Class II complete response which has a six-month review period from the date of resubmission, and set a PDUFA target action date of June 29, 2026.

30. The above statements identified in ¶¶ 21-29 were materially false and/or misleading, and failed to disclose material adverse facts about the Company's business, operations, and prospects. Specifically, Defendants failed to disclose to investors: (1) that the Company had not inspected its third-party manufacturing vendor's facility or otherwise audited the facility's compliance with current good manufacturing practices; (2) that, as a result, the Company lacked a reasonable basis to believe that the vendor had resolved the FDA's cited deficiencies; (3) that there was an undisclosed risk that the FDA would require additional information about the vendor's facility's manufacturing practices; (4) that, as a result of the foregoing, the regulatory approval of OLC was reasonably likely to be delayed; and (5) that, as a result of the foregoing, Defendants' positive statements about the Company's business, operations, and prospects were materially misleading and/or lacked a reasonable basis.

Disclosures at the End of the Class Period

31. On June 30, 2026, before the market opened, Unicycive disclosed that the FDA had issued a second Complete Response Letter regarding the Company's resubmitted New Drug Application for oxylanthanum, identifying the "***same third-party manufacturing deficiencies that were identified in the previous CRL issued in June 2025***." The Company claimed the "NDA for OLC had been resubmitted based on Unicycive's belief of continued progress by the original third-party manufacturing vendor in resolving FDA-cited deficiencies and demonstrating inspection

readiness." Specifically, on that date, the Company issued a press release which stated as follows, in relevant part:

> **Unicycive Therapeutics Receives Complete Response Letter from FDA Regarding Resubmitted Oxylanthanum Carbonate (OLC) New Drug Application (NDA)**
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> *-- Complete Response Letter relates to deficiencies previously identified at third-party manufacturing vendor --*
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> *-- FDA inspection of third-party facility did not occur during the NDA resubmission review --*
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> *-- Labeling discussions currently underway; latest communication received by the Company from FDA on June 29 regarding carton and container label --*
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> *-- FDA did not raise concerns regarding the clinical efficacy or safety data of OLC, and no additional data was requested --*
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> MOUNTAIN VIEW, Calif., June 30, 2026 (GLOBE NEWSWIRE) -- Unicycive Therapeutics, Inc. (Nasdaq: UNCY), a clinical-stage biotechnology company developing therapies for patients with kidney disease, today announced that it has received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) regarding the resubmitted New Drug Application (NDA) for oxylanthanum carbonate (OLC) for the treatment of hyperphosphatemia in patients with chronic kidney disease (CKD) on dialysis. The FDA has not raised any concerns regarding clinical efficacy or safety data, and no additional data was requested from Unicycive.
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> ***The CRL is based on the same third-party manufacturing deficiencies that were identified in the previous CRL issued in June 2025. Unicycive understands that the FDA has not yet conducted its inspection of that third-party manufacturing vendor as part of the review process of the resubmitted NDA. The NDA for OLC had been resubmitted based on Unicycive's belief of continued progress by the original third-party manufacturing vendor in resolving FDA-cited deficiencies and demonstrating inspection readiness.*** Unicycive previously discussed these milestones during a Type A meeting with the FDA in September 2025, which was held to obtain feedback and alignment on resolving the deficiencies identified in the Company's CRL related to the compliance status of the vendor. The FDA did not express any concerns about the third-party manufacturer's progress and no additional issues were raised by the FDA at the Type A meeting.
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> "We remain confident in the efficacy and safety of OLC," said Shalabh Gupta, M.D., Chief Executive Officer of Unicycive. "We are in active and ongoing discussion with the FDA regarding label and packaging, and we are optimistic that there will be a successful inspection of the third-party manufacturing vendor and that we will be able to expeditiously resubmit the NDA."
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> The OLC 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 chronic kidney disease (CKD) patients on dialysis, multiple preclinical studies, as well as chemistry, manufacturing and controls (CMC) data.

32. On this news, Unicycive's stock price fell $3.01, or 39.1%, to close at $4.69 per share on June 30, 2026, on unusually heavy trading volume.

CLASS ACTION ALLEGATIONS

33. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a class, consisting of all persons and entities that purchased or otherwise acquired Unicycive securities between December 29, 2025 and June 29, 2026, inclusive, and who were damaged thereby (the "Class"). Excluded from the Class are Defendants, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors, or assigns, and any entity in which Defendants have or had a controlling interest.

34. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Unicycive's shares actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can only be ascertained through appropriate discovery, Plaintiff believes that there are at least hundreds or thousands of members in the proposed Class. Millions of Unicycive shares were traded publicly during the Class Period on the NASDAQ. Record owners and other members of the Class may be identified from records maintained by Unicycive or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

35. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

36. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation.

37. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

(a) whether the federal securities laws were violated by Defendants' acts as alleged herein;

(b) whether statements made by Defendants to the investing public during the Class Period omitted and/or misrepresented material facts about the business, operations, and prospects of Unicycive; and

(c) to what extent the members of the Class have sustained damages and the proper measure of damages.

38. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation makes it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

UNDISCLOSED ADVERSE FACTS

39. The market for Unicycive's securities was open, well-developed and efficient at all relevant times. As a result of these materially false and/or misleading statements, and/or failures to disclose, Unicycive's securities traded at artificially inflated prices during the Class Period. Plaintiff and other members of the Class purchased or otherwise acquired Unicycive's securities relying upon the integrity of the market price of the Company's securities and market information relating to Unicycive, and have been damaged thereby.

40. During the Class Period, Defendants materially misled the investing public, thereby inflating the price of Unicycive's securities, by publicly issuing false and/or misleading statements and/or omitting to disclose material facts necessary to make Defendants' statements, as set forth herein, not false and/or misleading. The statements and omissions were materially false and/or misleading because they failed to disclose material adverse information and/or misrepresented the truth about Unicycive's business, operations, and prospects as alleged herein.

41. At all relevant times, the material misrepresentations and omissions particularized in this Complaint directly or proximately caused or were a substantial contributing cause of the damages sustained by Plaintiff and other members of the Class. As described herein, during the

Class Period, Defendants made or caused to be made a series of materially false and/or misleading statements about Unicycive's financial well-being and prospects. These material misstatements and/or omissions had the cause and effect of creating in the market an unrealistically positive assessment of the Company and its financial well-being and prospects, thus causing the Company's securities to be overvalued and artificially inflated at all relevant times. Defendants' materially false and/or misleading statements during the Class Period resulted in Plaintiff and other members of the Class purchasing the Company's securities at artificially inflated prices, thus causing the damages complained of herein when the truth was revealed.

LOSS CAUSATION

42. Defendants' wrongful conduct, as alleged herein, directly and proximately caused the economic loss suffered by Plaintiff and the Class.

43. During the Class Period, Plaintiff and the Class purchased Unicycive's securities at artificially inflated prices and were damaged thereby. The price of the Company's securities significantly declined when the misrepresentations made to the market, and/or the information alleged herein to have been concealed from the market, and/or the effects thereof, were revealed, causing investors' losses.

SCIENTER ALLEGATIONS

44. As alleged herein, Defendants acted with scienter since Defendants knew that the public documents and statements issued or disseminated in the name of the Company were materially false and/or misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws. As set forth elsewhere herein in detail, the Individual Defendants, by virtue of their receipt of information reflecting the true facts regarding Unicycive, their control over, and/or receipt and/or modification of Unicycive's allegedly materially misleading misstatements and/or their associations with the Company which made them privy to confidential proprietary information concerning Unicycive, participated in the fraudulent scheme alleged herein.

APPLICABILITY OF PRESUMPTION OF RELIANCE

(FRAUD-ON-THE-MARKET DOCTRINE)

45. The market for Unicycive's securities was open, well-developed and efficient at all relevant times. As a result of the materially false and/or misleading statements and/or failures to disclose, Unicycive's securities traded at artificially inflated prices during the Class Period. On May 14, 2026, the Company's share price closed at a Class Period high of $8.56 per share. Plaintiff and other members of the Class purchased or otherwise acquired the Company's securities relying upon the integrity of the market price of Unicycive's securities and market information relating to Unicycive, and have been damaged thereby.

46. During the Class Period, the artificial inflation of Unicycive's shares was caused by the material misrepresentations and/or omissions particularized in this Complaint causing the damages sustained by Plaintiff and other members of the Class. As described herein, during the Class Period, Defendants made or caused to be made a series of materially false and/or misleading statements about Unicycive's business, prospects, and operations. These material misstatements and/or omissions created an unrealistically positive assessment of Unicycive and its business, operations, and prospects, thus causing the price of the Company's securities to be artificially inflated at all relevant times, and when disclosed, negatively affected the value of the Company shares. Defendants' materially false and/or misleading statements during the Class Period resulted in Plaintiff and other members of the Class purchasing the Company's securities at such artificially inflated prices, and each of them has been damaged as a result.

47. At all relevant times, the market for Unicycive's securities was an efficient market for the following reasons, among others:

(a) Unicycive shares met the requirements for listing, and was listed and actively traded on the NASDAQ, a highly efficient and automated market;

(b) As a regulated issuer, Unicycive filed periodic public reports with the SEC and/or the NASDAQ;

(c) Unicycive regularly communicated with public investors via established market communication mechanisms, including through regular dissemination of press releases on

the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and/or

(d) Unicycive was followed by securities analysts employed by brokerage firms who wrote reports about the Company, and these reports were distributed to the sales force and certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace.

48. As a result of the foregoing, the market for Unicycive's securities promptly digested current information regarding Unicycive from all publicly available sources and reflected such information in Unicycive's share price. Under these circumstances, all purchasers of Unicycive's securities during the Class Period suffered similar injury through their purchase of Unicycive's securities at artificially inflated prices and a presumption of reliance applies.

49. A Class-wide presumption of reliance is also appropriate in this action under the Supreme Court's holding in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972), because the Class's claims are, in large part, grounded on Defendants' material misstatements and/or omissions. Because this action involves Defendants' failure to disclose material adverse information regarding the Company's business operations and financial prospects—information that Defendants were obligated to disclose—positive proof of reliance is not a prerequisite to recovery. All that is necessary is that the facts withheld be material in the sense that a reasonable investor might have considered them important in making investment decisions. Given the importance of the Class Period material misstatements and omissions set forth above, that requirement is satisfied here.

NO SAFE HARBOR

50. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this Complaint. The statements alleged to be false and misleading herein all relate to then-existing facts and conditions. In addition, to the extent certain of the statements alleged to be false may be characterized as forward looking, they were not identified as "forward-looking statements" when made and there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. In the alternative, to the

extent that the statutory safe harbor is determined to apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the speaker had actual knowledge that the forward-looking statement was materially false or misleading, and/or the forward-looking statement was authorized or approved by an executive officer of Unicycive who knew that the statement was false when made.

FIRST CLAIM

Violation of Section 10(b) of The Exchange Act and

Rule 10b-5 Promulgated Thereunder

Against All Defendants

51. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

52. During the Class Period, Defendants carried out a plan, scheme and course of conduct which was intended to and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; and (ii) cause Plaintiff and other members of the Class to purchase Unicycive's securities at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each defendant, took the actions set forth herein.

53. Defendants (i) employed devices, schemes, and artifices to defraud; (ii) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (iii) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities in an effort to maintain artificially high market prices for Unicycive's securities in violation of Section 10(b) of the Exchange Act and Rule 10b-5. All Defendants are sued either as primary participants in the wrongful and illegal conduct charged herein or as controlling persons as alleged below.

54. Defendants, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a

continuous course of conduct to conceal adverse material information about Unicycive's financial well-being and prospects, as specified herein.

55. Defendants employed devices, schemes and artifices to defraud, while in possession of material adverse non-public information and engaged in acts, practices, and a course of conduct as alleged herein in an effort to assure investors of Unicycive's value and performance and continued substantial growth, which included the making of, or the participation in the making of, untrue statements of material facts and/or omitting to state material facts necessary in order to make the statements made about Unicycive and its business operations and future prospects in light of the circumstances under which they were made, not misleading, as set forth more particularly herein, and engaged in transactions, practices and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities during the Class Period.

56. Each of the Individual Defendants' primary liability and controlling person liability arises from the following facts: (i) the Individual Defendants were high-level executives and/or directors at the Company during the Class Period and members of the Company's management team or had control thereof; (ii) each of these defendants, by virtue of their responsibilities and activities as a senior officer and/or director of the Company, was privy to and participated in the creation, development and reporting of the Company's internal budgets, plans, projections and/or reports; (iii) each of these defendants enjoyed significant personal contact and familiarity with the other defendants and was advised of, and had access to, other members of the Company's management team, internal reports and other data and information about the Company's finances, operations, and sales at all relevant times; and (iv) each of these defendants was aware of the Company's dissemination of information to the investing public which they knew and/or recklessly disregarded was materially false and misleading.

57. Defendants had actual knowledge of the misrepresentations and/or omissions of material facts set forth herein, or acted with reckless disregard for the truth in that they failed to ascertain and to disclose such facts, even though such facts were available to them. Such defendants' material misrepresentations and/or omissions were done knowingly or recklessly and for the purpose and effect of concealing Unicycive's financial well-being and prospects from the investing public

and supporting the artificially inflated price of its securities. As demonstrated by Defendants' overstatements and/or misstatements of the Company's business, operations, financial well-being, and prospects throughout the Class Period, Defendants, if they did not have actual knowledge of the misrepresentations and/or omissions alleged, were reckless in failing to obtain such knowledge by deliberately refraining from taking those steps necessary to discover whether those statements were false or misleading.

58. As a result of the dissemination of the materially false and/or misleading information and/or failure to disclose material facts, as set forth above, the market price of Unicycive's securities was artificially inflated during the Class Period. In ignorance of the fact that market prices of the Company's securities were artificially inflated, and relying directly or indirectly on the false and misleading statements made by Defendants, or upon the integrity of the market in which the securities trades, and/or in the absence of material adverse information that was known to or recklessly disregarded by Defendants, but not disclosed in public statements by Defendants during the Class Period, Plaintiff and the other members of the Class acquired Unicycive's securities during the Class Period at artificially high prices and were damaged thereby.

59. At the time of said misrepresentations and/or omissions, Plaintiff and other members of the Class were ignorant of their falsity, and believed them to be true. Had Plaintiff and the other members of the Class and the marketplace known the truth regarding the problems that Unicycive was experiencing, which were not disclosed by Defendants, Plaintiff and other members of the Class would not have purchased or otherwise acquired their Unicycive securities, or, if they had acquired such securities during the Class Period, they would not have done so at the artificially inflated prices which they paid.

60. By virtue of the foregoing, Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

61. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases and sales of the Company's securities during the Class Period.

SECOND CLAIM

Violation of Section 20(a) of The Exchange Act

Against the Individual Defendants

62. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

63. Individual Defendants acted as controlling persons of Unicycive within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of their high-level positions and their ownership and contractual rights, participation in, and/or awareness of the Company's operations and intimate knowledge of the false financial statements filed by the Company with the SEC and disseminated to the investing public, Individual Defendants had the power to influence and control and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various statements which Plaintiff contends are false and misleading. Individual Defendants were provided with or had unlimited access to copies of the Company's reports, press releases, public filings, and other statements alleged by Plaintiff to be misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

64. In particular, Individual Defendants had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same.

65. As set forth above, Unicycive and Individual Defendants each violated Section 10(b) and Rule 10b-5 by their acts and omissions as alleged in this Complaint. By virtue of their position as controlling persons, Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and other members of the Class suffered damages in connection with their purchases of the Company's securities during the Class Period.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief and judgment, as follows:

(a) Determining that this action is a proper class action under Rule 23 of the Federal Rules of Civil Procedure;

(b) Awarding compensatory damages in favor of Plaintiff and the other Class members against all defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

(c) Awarding Plaintiff and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

(d) Such other and further relief as the Court may deem just and proper.

JURY TRIAL DEMANDED

Plaintiff hereby demands a trial by jury.