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8 [Additional Counsel on Signature Page]

9 **UNITED STATES DISTRICT COURT**  
10 **NORTHERN DISTRICT OF CALIFORNIA**

11  
12 \_\_\_\_\_, Individually and on Behalf of  
All Others Similarly Situated,

13 Plaintiff,

14 v.

15 UNICYCIVE THERAPEUTICS, INC.,  
16 SHALABH GUPTA, AND JOHN  
TOWNSEND,  
17

Defendants.  
18

Case No.

**CLASS ACTION COMPLAINT FOR  
VIOLATIONS OF THE FEDERAL  
SECURITIES LAWS**

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

10 **NATURE OF THE ACTION AND OVERVIEW**

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

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

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

25 4. On June 30, 2026, before the market opened, Unicycive disclosed that the FDA had  
26 issued a Complete Response Letter regarding the Company’s resubmitted NDA for OLC,  
27  
28



1 the effects of the fraud have occurred in this Judicial District. Many of the acts charged herein,  
2 including the dissemination of materially false and/or misleading information, occurred in  
3 substantial part in this Judicial District. In addition, the Company's principal executive offices are  
4 located in this District.

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

9 **PARTIES**

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

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

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

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

21 16. Defendants Gupta and Townsend (collectively the "Individual Defendants"),  
22 because of their positions with the Company, possessed the power and authority to control the  
23 contents of the Company's reports to the SEC, press releases and presentations to securities analysts,  
24 money and portfolio managers and institutional investors, i.e., the market. The Individual  
25 Defendants were provided with copies of the Company's reports and press releases alleged herein  
26 to be misleading prior to, or shortly after, their issuance and had the ability and opportunity to  
27 prevent their issuance or cause them to be corrected. Because of their positions and access to  
28

1 material non-public information available to them, the Individual Defendants knew that the adverse  
2 facts specified herein had not been disclosed to, and were being concealed from, the public, and that  
3 the positive representations which were being made were then materially false and/or misleading.  
4 The Individual Defendants are liable for the false statements pleaded herein.

## 5 **SUBSTANTIVE ALLEGATIONS**

### 6 **Background**

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

9 18. Unicycive submitted an NDA, for its kidney disease therapy, oxylanthanum  
10 carbonate or OLC, to the FDA in September 2024. The NDA was accepted by the FDA in November  
11 2024. In June 2025, the FDA issued a CRL citing deficiencies at a third-party manufacturing vendor.  
12 Following the CRL, Unicycive held a Type A meeting with the FDA in October 2025 to discuss the  
13 single deficiency related to the third-party manufacturing vendor's compliance status. After  
14 receiving official meeting minutes and engaging with the vendor, Unicycive resubmitted the NDA  
15 in December 2025.

### 16 **Materially False and Misleading**

#### 17 **Statements Issued During the Class Period**

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

23 Specifically, the press release stated as follows, in relevant part:

#### 24 **Unicycive Therapeutics Announces Resubmission of New Drug Application (NDA) for Oxylanthanum Carbonate (OLC)**

25 \*

26 \*

27 \*

28 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)

1 to the U.S. Food and Drug Administration (FDA) for oxylanthanum carbonate  
2 (OLC), the Company's investigational oral phosphate binder for the treatment of  
hyperphosphatemia in patients with chronic kidney disease (CKD) on dialysis.

3 ***“Our original third-party manufacturing vendor has made significant progress  
4 toward regaining FDA compliance, allowing us to resubmit the OLC NDA as  
5 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.”

6 ***The NDA for OLC was resubmitted based on continued progress by the original  
7 third-party manufacturing vendor in resolving FDA-cited deficiencies and  
8 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.

10 20. On January 29, 2026, the Company announced “the U.S. Food and Drug  
11 Administration (FDA) has accepted the resubmission of its New Drug Application (NDA) for  
12 oxylanthanum carbonate (OLC).” The press release touted, among other things, that the “NDA is  
13 supported by data from three clinical studies . . . multiple preclinical studies as well as chemistry,  
14 manufacturing and controls (CMC) data.” Specifically, the press release stated as follows, in  
15 relevant part:  
16

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

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

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

21 LOS ALTOS, Calif., Jan. 29, 2026 (GLOBE NEWSWIRE) -- Unicycive  
22 Therapeutics, Inc. (“Unicycive” or the “Company”) (Nasdaq: UNCY), a clinical-  
stage biotechnology company developing therapies for patients with kidney disease,  
23 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  
24 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.  
25

26 “We are pleased that the agency has promptly accepted the resubmission of our NDA  
27 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  
28

1 chronic kidney disease (CKD) on dialysis who continue to struggle with  
2 hyperphosphatemia.”

3 *The NDA is supported by data from three clinical studies (a Phase 1 study in*  
4 *healthy volunteers, a bioequivalence study in healthy volunteers and a tolerability*  
5 *study of OLC in CKD patients on dialysis), multiple preclinical studies as well as*  
6 *chemistry, manufacturing and controls (CMC) data. The FDA did not raise any*  
7 *concerns regarding OLC’s preclinical, clinical, or safety data included in the*  
8 *original NDA submission.*

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

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

#### 18 **Key Highlights & Upcoming Milestones**

19 • In January 2026, the Company announced the FDA has accepted the resubmission  
20 of its NDA for OLC, an investigational oral phosphate binder for the treatment of  
21 hyperphosphatemia in patients with CKD on dialysis. The FDA set a PDUFA target  
22 action date of June 29, 2026. The NDA is supported by data from three clinical  
23 studies (a Phase 1 study in healthy volunteers, a bioequivalence study in healthy  
24 volunteers and a tolerability study in patients with CKD on dialysis), multiple  
25 preclinical studies and chemistry, manufacturing and controls (CMC) data. The FDA  
26 did not raise any concerns regarding the preclinical, clinical or safety data for OLC  
27 included in the original NDA submission. *The resubmission in December 2025 was*  
28 *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.

#### 29 **Financial Results for the Year Ended December 31, 2025**

30 \* \* \*

31 Other income was \$3.0 million for the year ended December 31, 2025 compared to  
32 Other expense of \$4.6 million in the same period in 2024 due primarily to a decrease  
33 in the fair value of the Company’s warrant liability.

34 Net loss attributable to common stockholders for the year ended December 31, 2025  
35 was \$26.6 million, or \$1.67 per share of common stock, compared to a net loss

1       attributable to common stockholders of \$37.8 million, or \$5.65 per share of common  
2       stock for the same period in 2024. The decreased net loss for the year ended  
3       December 31, 2025, was attributable primarily to the decrease in drug development  
4       and clinical trial costs.

5       As of March 30, 2026 unaudited cash, cash equivalents, and marketable securities  
6       totaled \$54.9 million. The Company believes that it has sufficient resources to fund  
7       planned operations into 2027.

8       22.       On March 30, 2026, the Company submitted its annual report for the fiscal year  
9       ended December 31, 2025 on a Form 10-K filed with the SEC (the “FY25 10-K”). The FY25 10-K  
10       affirmed the previously reported financial results. The FY25 10-K further touted the Company’s  
11       progress with its CRL for OLC, including that the Company had discussed the *“resolution of the  
12       single deficiency identified in the CRL related to the compliance status of a third-party  
13       manufacturing vendor”* and that *“[f]ollowing receipt of the official meeting minutes from the  
14       Type A meeting and engaging in discussions with its third-party manufacturing vendor, we  
15       resubmitted its NDA to the FDA in December 2025.”* Specifically, the FY25 10-K stated as follows,  
16       in relevant part:

17       We are seeking the U.S. Food and Drug Administration (FDA) approval of OLC via  
18       the 505(b)(2) regulatory pathway. In September 2024, we submitted a New Drug  
19       Application (NDA) for OLC to the FDA. In November 2024 we announced the FDA  
20       had accepted its NDA and set a Prescription Drug User Fee Act (PDUFA) target  
21       action date of June 28, 2025. In June 2025, the FDA issued us a Complete Response  
22       Letter (CRL) notifying us that a third-party manufacturing vendor of its main  
23       contract development and manufacturing organization (CDMO) was cited for  
24       deficiencies following a cGMP inspection. No other concerns have been identified  
25       to us, including pre-clinical, clinical, or safety data submitted as part of the NDA. *In  
26       October 2025, we held a Type A meeting with the FDA to discuss the resolution of  
27       the single deficiency identified in the CRL related to the compliance status of a  
28       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.*

29       23.       The FY25 10-K further purported to warn of risks which “*could*” or “*may*”  
30       negatively impact the Company, including those related to maintaining “current Good  
31       Manufacturing Practices (cGMP)” for OLC.

1 Manufacturing Practice (“cGMP”) requirements for product facilities.” Specifically, the FY25 10-  
2 K stated as follows, in relevant part:

3 *Any product candidate for which we obtain marketing approval could be subject*  
4 *to marketing restrictions or withdrawal from the market and we may be subject to*  
5 *penalties if we fail to comply with regulatory requirements or if we experience*  
*unanticipated problems with our products.*

6 Any product candidate for which we obtain marketing approval, along with the  
7 manufacturing processes and facilities, post-approval clinical data, labeling,  
8 advertising and promotional activities for such product, will be subject to continual  
9 requirements of and review by the FDA and other regulatory authorities. *These*  
10 *requirements include submissions of promotional materials and safety and other*  
11 *post-marketing information and reports, registration and listing requirements,*  
12 *current Good Manufacturing Practice (“cGMP”) requirements for product*  
13 *facilities, quality assurance* and corresponding maintenance of records and  
14 documents and requirements regarding the distribution of samples to physicians and  
15 related recordkeeping.

16 \* \* \*

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

18 We rely on suppliers, vendors and partners for certain key aspects of our business,  
19 including support for information technology systems and certain human resource  
20 functions. We do not control these partners, but we depend on them in ways that may  
21 be significant to us. *For example, our third-party manufacturing vendor of its main*  
22 *contract development and manufacturing organization (CDMO) was cited for*  
23 *deficiencies following a cGMP inspection resulting in the FDA issuing us a CRL*  
24 *for our initial NDA submission which resulted in us having to resubmit an NDA*  
25 *causing delay in our target action PFUDA date of 12-months. If these parties fail*  
26 *to meet our expectations or fulfill their obligations to us, we may fail to receive the*  
27 *expected benefits.* In addition, if any of these third parties fails to comply with  
28 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.

\* \* \*

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.*

1           24.     On May 12, 2026, Unicycive issued a press release announcing its financial results  
2 for the first quarter ended March 31, 2026 and provided a business update. The press release touted,  
3 among other things, that “U.S. Food and Drug Administration (FDA) review of oxylanthanum  
4 carbonate (OLC) New Drug Application (NDA) resubmission remains on track, with a Prescription  
5 Drug User Fee Act (PDUFA) target action date of June 29, 2026.” Specifically, the press release  
6 stated as follows, in relevant part:  
7

8           **Unicycive Therapeutics Announces First Quarter 2026 Financial Results and  
9 Provides Business Update**

10           *U.S. Food and Drug Administration (FDA) review of oxylanthanum carbonate  
11 (OLC) New Drug Application (NDA) resubmission remains on track, with a  
12 Prescription Drug User Fee Act (PDUFA) target action date of June 29, 2026*

13           *Commercial readiness activities continue in anticipation of the potential commercial  
14 launch of OLC*

15           **MOUNTAIN VIEW, Calif., May 12, 2026** -- Unicycive Therapeutics,  
16 Inc. (Nasdaq: UNCY), a clinical-stage biotechnology company developing therapies  
17 for patients with kidney disease, today announced its financial results for the first  
18 quarter ended March 31, 2026, and provided a business update.

19           *“As we approach the June 29th PDUFA target action date, we remain optimistic  
20 about the potential approval of OLC and focused on preparations for the  
21 subsequent launch of OLC,” said Shalabh Gupta, M.D., Chief Executive Officer  
22 of Unicycive. “Our ongoing dialogue with the FDA during the review cycle has  
23 been constructive and timely. Uncontrolled hyperphosphatemia remains a  
24 significant health concern, affecting nearly 75% of U.S. patients with chronic kidney  
25 disease who are undergoing dialysis. OLC has the potential to improve adherence  
26 and phosphorus control with reduced pill burden, compared with currently available  
27 phosphate binders.”*

28           **Key Highlights & Upcoming Milestones**

•     *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.*

\*

\*

\*

**Financial Results for the Quarter Ended March 31, 2026**

1 As of May 11, 2026, unaudited cash, cash equivalents, and marketable securities  
2 totaled \$57.1 million. The Company believes that it has sufficient resources to fund  
planned operations into 2027.

3 \* \* \*

4 Other income (expense) was \$(4.4) million expense for the quarter ended March 31,  
5 2026, compared to \$8.6 million income for the three months ended March 31, 2025,  
6 attributed primarily to an increase in the fair value of the Company's warrant  
liability.

7 25. On May 12, 2026, the Company submitted its quarterly report for the period ended  
8 March 31, 2026 on a Form 10-Q filed with the SEC, affirming the previously reported financial  
9 results. The report touted the Company's progress with its CRL for OLC, including that the  
10 Company had discussed the ***"resolution of the single deficiency identified in the CRL related to***  
11 ***the compliance status of a third-party manufacturing vendor"*** and that ***"[f]ollowing receipt of the***  
12 ***official meeting minutes from the Type A meeting and engaging in discussions with its third-party***  
13 ***manufacturing vendor, we resubmitted its NDA to the FDA in December 2025."*** Specifically, the  
14 quarterly report stated as follows, in relevant part:

15  
16 On October 28, 2025, we announced an update from our meeting with the U.S. Food  
17 and Drug Administration (FDA) and timing of the resubmission of our New Drug  
18 Application (NDA) for Oxylanthanum carbonate (OLC) following receipt of a CRL  
19 on June 30, 2025. The Type A FDA meeting was held to discuss the ***resolution of***  
20 ***the single deficiency identified in the CRL related to the compliance status of a***  
21 ***third-party manufacturing vendor. No other concerns have been identified to us,***  
22 ***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.

23 26. The above statements identified in ¶¶ 19-25 were materially false and/or misleading,  
24 and failed to disclose material adverse facts about the Company's business, operations, and  
25 prospects. Specifically, Defendants failed to disclose to investors: (1) the FDA had not scheduled  
26 or conducted the reinspection that was the basis of the original CRL rejection of the OLC NDA; (2)  
27 the OLC NDA resubmission was therefore unlikely to be approved by the PDUFA target date  
28 without a reinspection of the relevant third party manufacturer of OLC, which had yet to occur; and

(3) 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**

27. 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 further revealed 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)**

*-- Complete Response Letter relates to deficiencies previously identified at third-party manufacturing vendor --*

*-- FDA inspection of third-party facility did not occur during the NDA resubmission review --*

*-- Labeling discussions currently underway; latest communication received by the Company from FDA on June 29 regarding carton and container label --*

*-- FDA did not raise concerns regarding the clinical efficacy or safety data of OLC, and no additional data was requested --*

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.

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

1 A meeting with the FDA in September 2025, which was held to obtain feedback and  
2 alignment on resolving the deficiencies identified in the Company's CRL related to  
3 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.

4 "We remain confident in the efficacy and safety of OLC," said Shalabh Gupta, M.D.,  
5 Chief Executive Officer of Unicycive. "We are in active and ongoing discussion with  
6 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."

7 The OLC NDA is supported by data from three clinical studies: a Phase 1 study in  
8 healthy volunteers, a bioequivalence study in healthy volunteers, and a tolerability  
9 study of OLC in chronic kidney disease (CKD) patients on dialysis, multiple  
preclinical studies, as well as chemistry, manufacturing and controls (CMC) data.

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

#### 12 **CLASS ACTION ALLEGATIONS**

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

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

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

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

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

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

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

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

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

21                                   **UNDISCLOSED ADVERSE FACTS**

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

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

7           37. At all relevant times, the material misrepresentations and omissions particularized in  
8 this Complaint directly or proximately caused or were a substantial contributing cause of the  
9 damages sustained by Plaintiff and other members of the Class. As described herein, during the  
10 Class Period, Defendants made or caused to be made a series of materially false and/or misleading  
11 statements about Unicycive's financial well-being and prospects. These material misstatements  
12 and/or omissions had the cause and effect of creating in the market an unrealistically positive  
13 assessment of the Company and its financial well-being and prospects, thus causing the Company's  
14 securities to be overvalued and artificially inflated at all relevant times. Defendants' materially false  
15 and/or misleading statements during the Class Period resulted in Plaintiff and other members of the  
16 Class purchasing the Company's securities at artificially inflated prices, thus causing the damages  
17 complained of herein when the truth was revealed.

#### 18                                   **LOSS CAUSATION**

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

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

#### 26                                   **SCIENTER ALLEGATIONS**

27           40. As alleged herein, Defendants acted with scienter since Defendants knew that the  
28 public documents and statements issued or disseminated in the name of the Company were

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

9 **APPLICABILITY OF PRESUMPTION OF RELIANCE**

10 **(FRAUD-ON-THE-MARKET DOCTRINE)**

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

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

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

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

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

7                   (c)     Unicycive regularly communicated with public investors via established  
8 market communication mechanisms, including through regular dissemination of press releases on  
9 the national circuits of major newswire services and through other wide-ranging public disclosures,  
10 such as communications with the financial press and other similar reporting services; and/or

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

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

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

1 **NO SAFE HARBOR**

2 46. The statutory safe harbor provided for forward-looking statements under certain  
3 circumstances does not apply to any of the allegedly false statements pleaded in this Complaint. The  
4 statements alleged to be false and misleading herein all relate to then-existing facts and conditions.  
5 In addition, to the extent certain of the statements alleged to be false may be characterized as forward  
6 looking, they were not identified as “forward-looking statements” when made and there were no  
7 meaningful cautionary statements identifying important factors that could cause actual results to  
8 differ materially from those in the purportedly forward-looking statements. In the alternative, to the  
9 extent that the statutory safe harbor is determined to apply to any forward-looking statements  
10 pleaded herein, Defendants are liable for those false forward-looking statements because at the time  
11 each of those forward-looking statements was made, the speaker had actual knowledge that the  
12 forward-looking statement was materially false or misleading, and/or the forward-looking statement  
13 was authorized or approved by an executive officer of Unicycive who knew that the statement was  
14 false when made.

15 **FIRST CLAIM**

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

17 **Rule 10b-5 Promulgated Thereunder**

18 **Against All Defendants**

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

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

27 49. Defendants (i) employed devices, schemes, and artifices to defraud; (ii) made untrue  
28 statements of material fact and/or omitted to state material facts necessary to make the statements

1 not misleading; and (iii) engaged in acts, practices, and a course of business which operated as a  
2 fraud and deceit upon the purchasers of the Company's securities in an effort to maintain artificially  
3 high market prices for Unicycive's securities in violation of Section 10(b) of the Exchange Act and  
4 Rule 10b-5. All Defendants are sued either as primary participants in the wrongful and illegal  
5 conduct charged herein or as controlling persons as alleged below.

6 50. Defendants, individually and in concert, directly and indirectly, by the use, means or  
7 instrumentalities of interstate commerce and/or of the mails, engaged and participated in a  
8 continuous course of conduct to conceal adverse material information about Unicycive's financial  
9 well-being and prospects, as specified herein.

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

19 52. Each of the Individual Defendants' primary liability and controlling person liability  
20 arises from the following facts: (i) the Individual Defendants were high-level executives and/or  
21 directors at the Company during the Class Period and members of the Company's management team  
22 or had control thereof; (ii) each of these defendants, by virtue of their responsibilities and activities  
23 as a senior officer and/or director of the Company, was privy to and participated in the creation,  
24 development and reporting of the Company's internal budgets, plans, projections and/or reports;  
25 (iii) each of these defendants enjoyed significant personal contact and familiarity with the other  
26 defendants and was advised of, and had access to, other members of the Company's management  
27 team, internal reports and other data and information about the Company's finances, operations, and  
28 sales at all relevant times; and (iv) each of these defendants was aware of the Company's

1 dissemination of information to the investing public which they knew and/or recklessly disregarded  
2 was materially false and misleading.

3         53. Defendants had actual knowledge of the misrepresentations and/or omissions of  
4 material facts set forth herein, or acted with reckless disregard for the truth in that they failed to  
5 ascertain and to disclose such facts, even though such facts were available to them. Such defendants'  
6 material misrepresentations and/or omissions were done knowingly or recklessly and for the purpose  
7 and effect of concealing Unicycive's financial well-being and prospects from the investing public  
8 and supporting the artificially inflated price of its securities. As demonstrated by Defendants'  
9 overstatements and/or misstatements of the Company's business, operations, financial well-being,  
10 and prospects throughout the Class Period, Defendants, if they did not have actual knowledge of the  
11 misrepresentations and/or omissions alleged, were reckless in failing to obtain such knowledge by  
12 deliberately refraining from taking those steps necessary to discover whether those statements were  
13 false or misleading.

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

23         55. At the time of said misrepresentations and/or omissions, Plaintiff and other members  
24 of the Class were ignorant of their falsity, and believed them to be true. Had Plaintiff and the other  
25 members of the Class and the marketplace known the truth regarding the problems that Unicycive  
26 was experiencing, which were not disclosed by Defendants, Plaintiff and other members of the Class  
27 would not have purchased or otherwise acquired their Unicycive securities, or, if they had acquired  
28

1 such securities during the Class Period, they would not have done so at the artificially inflated prices  
2 which they paid.

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

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

8 **SECOND CLAIM**

9 **Violation of Section 20(a) of The Exchange Act**

10 **Against the Individual Defendants**

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

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

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

61. 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.

1 DATED: \_\_\_\_\_, 2026

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