UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **December 28, 2022**

Unicycive Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-40582**	**81-3638692**
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	IRS Employer Identification No.)

4300 El Camino Real, Suite 210
Los Alto, CA 94022
(Address of principal executive offices)

Registrant's telephone number, including area code: **(650) 351-4495**

(Former name or former address, if changed since last report)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class:	**Trading Symbol(s)**	**Name of each exchange on which registered:**
Common Stock	UNCY	Nasdaq Capital Market

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communication pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter). Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure.

On December 28, 2022, Unicycive Therapeutics, Inc. (the "Company") issued a press release announcing it achieved primary endpoint in pivotal bioequivalence study of Renazorb. A copy of the press release is furnished as Exhibit 99.1 to this Form 8-K. In addition, the Company is filing its corporate presentation with respect to the results of the pivotal bioequivalence study of Renazorb. A copy of the presentation materials is attached as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated herein by reference.

The information disclosed under this Item 7.01, including Exhibits 99.1 and 99.2 hereto, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall it be incorporated by reference into any registration statement or other document pursuant to the Securities Act of 1933, as amended, except as expressly set forth in such filing.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits.

99.1	Press Release of Unicycive Therapeutics, Inc. dated December 28, 2022.
99.2	Corporate Presentation of Unicycive Therapeutics, Inc.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto

duly authorized.

Dated: December 28, 2022

UNICYCIVE THERAPEUTICS, INC.

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

Exhibit 99.1

Unicycive Achieves Primary Endpoint in Pivotal Bioequivalence Study of Renazorb

Renazorb demonstrates pharmacodynamic bioequivalence to Fosrenol

Renazorb's enhanced product profile features reduced pill burden and small, swallowable tablets, which may improve patient compliance

On track to file New Drug Application mid-2023

LOS ALTOS, Calif., December 28, 2022 -- Unicycive Therapeutics, Inc. (Nasdaq: UNCY), a clinical-stage biotechnology company developing therapies for patients with kidney disease, today announced that the primary endpoint was met in the Company's pivotal bioequivalence (BE) study comparing Renazorb to Fosrenol®. Based on the topline results, pharmacodynamic (PD) BE of Renazorb to Fosrenol was established and met the regulatory criteria for PD BE in the healthy volunteer BE study.

Renazorb is an investigational phosphate binding agent utilizing proprietary nanoparticle technology that is being developed to treat hyperphosphatemia in chronic kidney disease (CKD) patients on dialysis. If approved, Renazorb may dramatically reduce the pill burden that patients endure with currently available medications. The global market opportunity for treating hyperphosphatemia is projected to be in excess of $2.5 billion in 2022, with the United States accounting for more than $1 billion of that total. Despite the availability of several U.S. Food and Drug Administration (FDA)-cleared medications, 75 percent of U.S. dialysis patients fail to achieve the target phosphorus levels recommended by published medical guidelines. Market research indicates that the top reason for this significant unmet medical need is related to the high pill burden, which leads to poor patient compliance.

Unicycive previously received confirmatory guidance from the FDA that this single BE study in healthy volunteers would satisfy all clinical regulatory requirements and that no other clinical studies would be required for a New Drug Application (NDA) filing through the 505(b)(2) pathway.

Today's positive results are from a randomized, open-label, two-way crossover BE study to establish PD BE between Renazorb and Fosrenol. The study enrolled 40 subjects per treatment arm. The study design, including the dose, primary endpoint, and sample size, was reviewed, and aligned by the FDA before the initiation of the study.

"We are delighted with the successful outcome of our registrational BE study of Renazorb. This is a major milestone for Unicycive that brings us one step closer to obtaining market approval for Renazorb to treat hyperphosphatemia," said Shalabh Gupta, M.D., Chief Executive Officer of Unicycive. "Our R&D team has extensive experience filing NDA submissions and a demonstrated track record of multiple product approvals from the FDA. We look forward to filing the NDA for Renazorb in mid-2023 and for its potential approval in order to benefit the multitude of hyperphosphatemia patients who are not well served by current treatment options."

The primary outcome measure of the BE study was Least Square (LS) mean change in urinary phosphate excretion (in mg/day) from baseline to the evaluation period (PD variable). Based on the mixed-effect linear model, the 90% Confidence Interval (CI) was constructed for the difference in PD variable for Renazorb and Fosrenol. In addition, the acceptable range was defined as ± 20% of the LS mean of the PD variability for Fosrenol. PD BE was achieved because the 90% CI was completely contained within the acceptable range.

About Renazorb (lanthanum dioxycarbonate)

Renazorb is an investigational next-generation lanthanum-based phosphate binding agent utilizing proprietary nanoparticle technology being developed for the treatment of hyperphosphatemia in patients with chronic kidney disease (CKD). Its potential best-in-class profile has meaningful patient adherence benefits over currently available treatment options as it requires smaller and fewer number of pills per dose and is swallowed instead of chewed.

About Hyperphosphatemia

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

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

Fosrenol is a registered trademark of Shire International Licensing BV.

About Unicycive Therapeutics

Unicycive Therapeutics is a biotechnology company developing novel treatments for kidney diseases. Unicycive's lead drug, Renazorb, is a novel phosphate binding agent being developed for the treatment of hyperphosphatemia. UNI-494 is a patent-protected new chemical entity in late preclinical development for the treatment of acute kidney injury. For more information, please visit www.unicycive.com.

Forward-looking statements

Certain statements in this press release are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995. These statements may be identified using words such as "anticipate," "believe," "forecast," "estimated" and "intend" or other similar terms or expressions that concern Unicycive's expectations, strategy, plans or intentions. These forward-looking statements are based on Unicycive's current expectations and actual results could differ materially. There are several factors that could cause actual events to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, clinical trials involve a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results; our clinical trials may be suspended or discontinued due to unexpected side effects or other safety risks that could preclude approval of our product candidates; risks related to business interruptions, including the outbreak of COVID-19 coronavirus, which could seriously harm our financial condition and increase our costs and expenses; dependence on key personnel; substantial competition; uncertainties of patent protection and litigation; dependence upon third parties; and risks related to failure to obtain FDA clearances or approvals and noncompliance with FDA regulations. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the uncertainties related to market conditions and other factors described more fully in the section entitled 'Risk Factors' in Unicycive's Annual Report on Form 10-

K for the year ended December 31, 2021, and other periodic reports filed with the Securities and Exchange Commission. Any forward-looking statements contained in this press release speak only as of the date hereof, and Unicycive specifically disclaims any obligation to update any forward-looking statement, whether as a result of new information, future events or otherwise.

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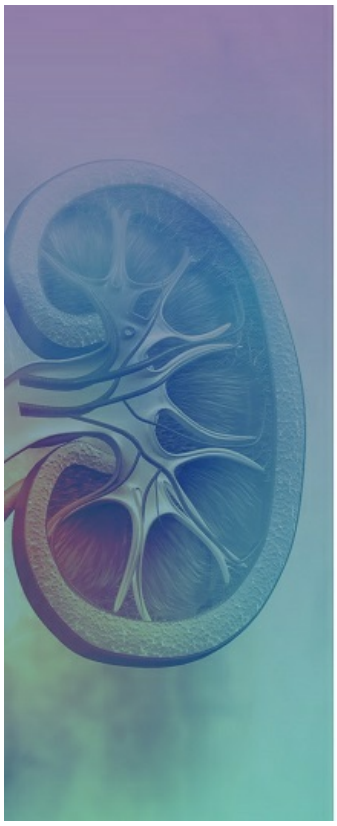
SOURCE: Unicycive Therapeutics, Inc.



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NASDAQ: UNCY

Renazorb: BE Study Update

Renazorb Background

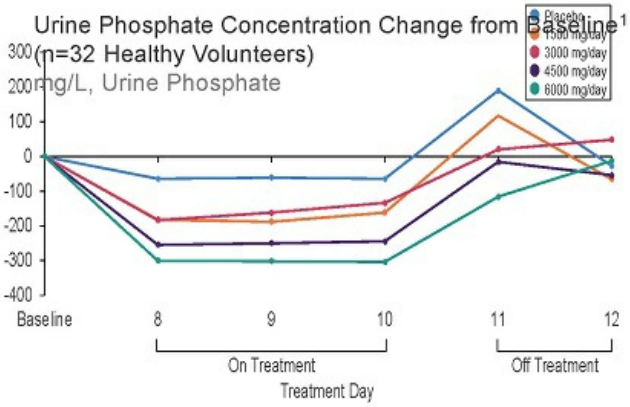
- **Renazorb**
  - Novel lanthanum-based phosphate binder
  - In development for the treatment of hyperphosphatemia in CKD patients on dialysis
- **Regulatory Pathway**
  - Agreement with the FDA on acceptability of 505(b)(2) pathway for registration
  - Followed FDA BE study guidance for the development of the protocol
  - Because of low systemic absorption of lanthanum, BE study is based on a pharmacodynamic-based endpoint rather than a pharmacokinetic-based endpoint
  - Agreement with the FDA on the study design, dose and endpoints for the BE study

Phase 1 Clinical Trial: Lanthanum Dioxycarbonate (LDC) was Well-Tolerated with Dose-Dependent Phosphate Lowering Effect

Study Design:
Open label, dose ranging study (evaluated 4 LDC doses : 1500, 3000, 4500 and 6000 mg/day), in N=32 healthy volunteers

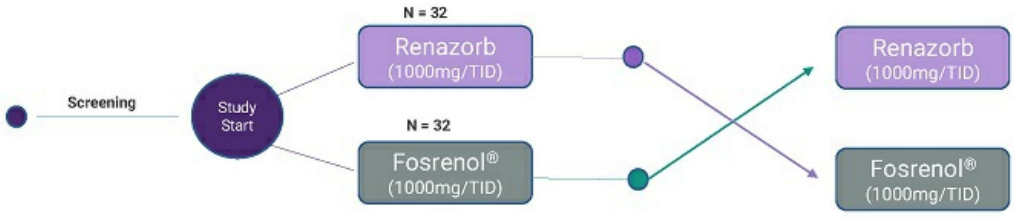
Primary endpoint: Phosphorus binding capacity
LDC showed statistically significant phosphate reduction with:
- ✓ 3000 mg/day (-159.59 mg/L)
- ✓ 4500 mg/day (-249.61 mg/L)
- ✓ 6000 mg/day (-301.57 mg/L)

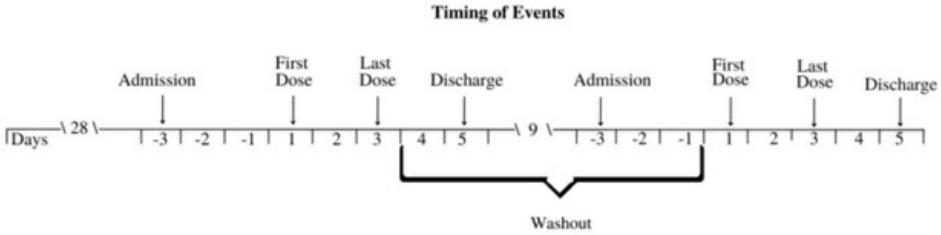
Secondary endpoint: Drug Safety
All treatment-related adverse events (AEs) were mild in severity. No severe or life-threatening AEs were reported



1 Baseline is the mean of phosphate concentrations from study day 2 to day 6
Note:Urine phosphate concentrations for each day is recorded on the morning of the following day at a 24-hour interval
SOURCE: Data on File [rzb-11-101-synoptic-csr.pdf]; Updated as of 3/8/22

Pivotal Bioequivalence Study Design





Renazorb Bioequivalence Study in Healthy Volunteers

UNICYCIVE THERAPEUTICS INC.

Objectives	**Primary Objective** To demonstrate pharmacodynamic (PD) equivalence of orally administered Renazorb 1000 mg TID to orally administered Fosrenol 1000 mg TID in healthy subjects **Secondary Objective** To compare the safety and tolerability of Renazorb versus Fosrenol in healthy subjects
Endpoints	**Primary Endpoint** Least squares (LS) mean change in urinary phosphate excretion (in mg/day) from baseline to the evaluation period. **Secondary Endpoint** Safety endpoints include incidence, frequency, and severity of treatment-emergent adverse events (TEAEs), including serious adverse events and adverse events (AEs) resulting in treatment discontinuation.

- Baseline is defined as the approximately 48-hour urine collection period starting on Day -2 and ending on Day 1.
- Evaluation period is defined as the approximately 72-hour urine collection period starting on Day 1 and ending on Day 4.

BE Study Meets Primary Endpoint

UNICYCIVE THERAPEUTICS INC.

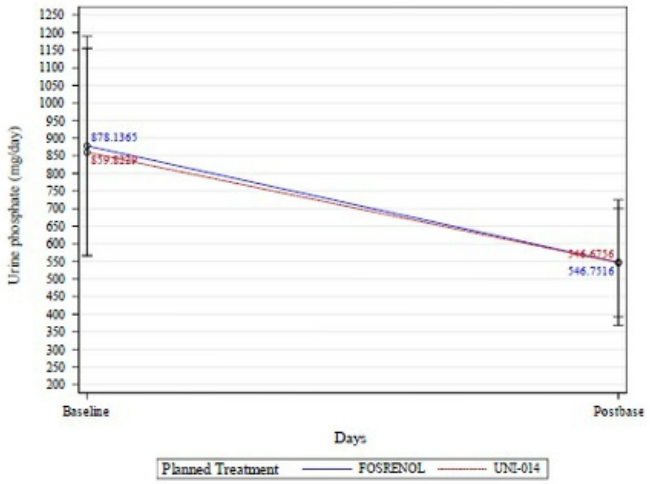
Summary of Mean Change in Urinary Phosphorus Excretion (mg/day)

Visit	Statistics	Renazorb	Fosrenol
	N	75	75
Baseline	LS Mean (SE)	859.8 (30.8)	878.1(30.8)
Evaluation Period	LS Mean (SE)	546.7 (19.3)	546.8 (19.3)
Change	LS Mean Change (SE)	-320.4 (17.7)	-324.0 (17.7)
90% CI for LS Mean Treatment difference Acceptance Range			-45.9, +53.2 -64.8, +64.8

- FDA requirement is to establish similarity of the primary endpoint (least-squares mean change from baseline) within a ± 20% range to Fosrenol (the reference-listed comparator)
- The results from our BE study satisfy FDA's requirement

BE Study Meets Primary Endpoint

Average of Daily Urinary Phosphorus Excretion (mg/day)
At baseline and over 3-day dosing period



Safety Comparable Between Renazorb and Fosrenol

- Treatment emergent adverse events were comparable between the Renazorb and Fosrenol groups
- No subjects in the study experienced a serious adverse event (requiring hospitalization or withdrawal from the study)
- There were no deaths in the study

Summary

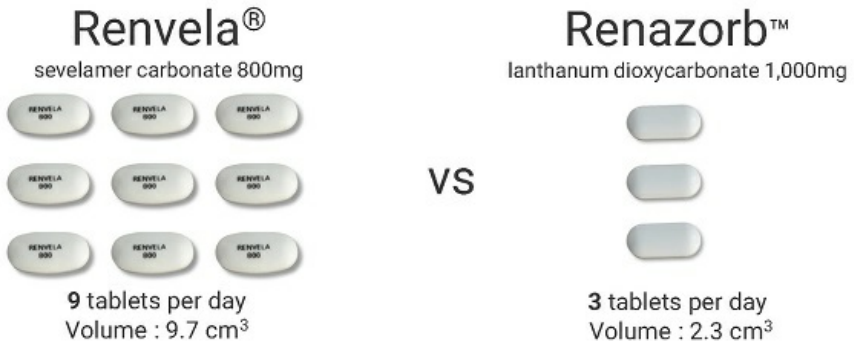
- **Efficacy**
  - Study met the primary endpoint
  - Bioequivalence established based on the pharmacodynamic endpoint
  - Reference interval was defined as ±20% of the LS mean of the primary PD variable for lanthanum carbonate
  - The 90% CI of the primary PD variable for Renazorb was completely contained within the reference interval
  - This approach is based on the statistical method for evaluation of bioequivalence described in various regulatory guidelines [FDA BE Study Guidance 2001; EMA Guidelines for Bioequivalence 2010 and FDA BE Study Guidance 2022]
- **Safety**
  - Comparable to Fosrenol

Successful Renazorb BE Study Outcome Establishes Bridge to Fosrenol Clinical Data

- By successfully demonstrating pharmacodynamic bioequivalence between Renazorb and Fosrenol (505(b)(2) reference-listed drug), a bridge to Fosrenol's already approved clinical efficacy and safety data set is established
  - 5 RCTs in CKD patients on dialysis (both hemodialysis and peritoneal dialysis)
  - 2,325 total patients studied
  - Clearly documented clinical efficacy
    - ~ 2.0 mg/dL reduction in serum phosphorus (compared to ~ 0.70 mg/dL for ARDX's tenapanor)
  - Established safety and tolerability
    - Incidence of adverse events (AEs) in pivotal phase 3 trial similar to placebo
  - Above clinical profile becomes Renazorb product label and can be used in promotion of our product

Renazorb Value Proposition

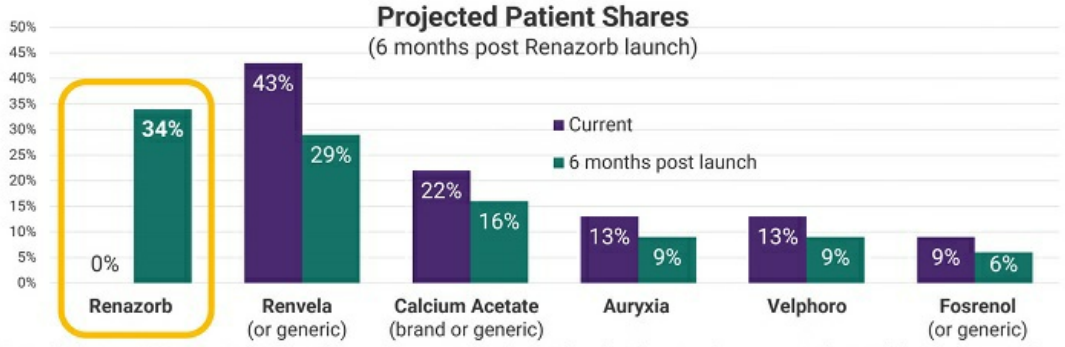
Through its proprietary nanoparticle technology, Unicycive has harnessed the phosphate binding potency of lanthanum to reduce the number and size of pills that patients must take to control hyperphosphatemia



Renazorb offers patients a 4-fold reduction in daily pill burden compared to Renvela—currently the most prescribed phosphate binder

Market Opportunity

- US phosphate binder market current over $1Billion
- CMS reimbursement change taking effect in 2025 will increase market substantially
- Market research indicates that Renazorb is poised to capture more than a third of the US market



Base: n=100 Nephrologists • Q22. Assuming Binder X (Renazorb) were 6 months post-launch with cost and coverage similar to Velphoro and Auryxia, how, if at all, would your prescribing change among your patients who are receiving a phosphate binder? Based on your previous answers we have populated your current phosphate binder prescribing by product below. Due to rounding and combination use, the sum may not be exactly 100%.

Source: Renazorb Conjoint Market Research Study, Reason Research, March 2022