November 14, 2022

# Unicycive Announces Third Quarter Financial Results and Provides Business Update

*Topline results by year-end as enrollment completed for pivotal bioequivalence study of RENAZORB™ (lanthanum dioxycarbonate), an investigational phosphate binder for the treatment of hyperphosphatemia in Chronic Kidney Disease (CKD) patients on dialysis*

*On track to file New Drug Application for RENAZORB in 2023*

*Expect clearance for a Phase 1 healthy volunteer study of UNI-494, a novel proprietary drug targeting the SUR2B subunit of the mitochondrial $K_{ATP}$ channel, in the UK by year-end*

LOS ALTOS, Calif., Nov. 14, 2022 (GLOBE NEWSWIRE) -- Unicycive Therapeutics, Inc. (Nasdaq: UNCY), a clinical-stage biotechnology company developing therapies for patients with kidney disease, today announced its financial results for the third quarter ended September 30, 2022, and provided a business update.

**Management Commentary**

“The third quarter of 2022 and recent weeks have been particularly productive as we completed enrollment of our pivotal bioequivalence trial of RENAZORB, with topline results expected by year-end. We remain on track to file a New Drug Application (NDA) in 2023,” said Shalabh Gupta, M.D., Chief Executive Officer of Unicycive. “In addition to signing our first global partnership for the marketing and commercialization of RENAZORB in China with Lee’s Pharmaceutical, we continue to make strides in advancing discussions for additional potential partnerships across Asia and Europe in order to bring the benefits of this exciting new medicine to hyperphosphatemia patients around the globe.”

Dr. Gupta added, “We were delighted to share favorable results from both our product candidates with the nephrology community at this year’s Kidney Week. The data we presented on RENAZORB demonstrated its ability to effectively reduce urinary phosphate excretion and underscored the daily pill burden of various phosphate binder therapies, further supporting RENAZORB’s potential best-in-class product profile. In addition, preclinical data on the pharmacokinetics of UNI-494 support its ability to reduce oxidative stress and restore mitochondrial function in several potential indications.”

“We continue to execute our strategy and remain excited about the opportunities ahead for Unicycive as we advance our clinical studies and expand access to RENAZORB globally. Additionally, we continue to elucidate UNI-494’s novel mechanism to improve mitochondrial function to treat a variety of diseases with large unmet medical needs and substantial market opportunities,” concluded Dr. Gupta.

**Program Updates**

*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) on dialysis. Its potential best-in-class profile may have 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.

- Recently completed enrollment of its pivotal bioequivalence (BE) study in healthy volunteers to demonstrate the comparability of RENAZORB to the reference listed drug, Fosrenol®. The design for the BE study was previously agreed upon with the U.S. Food and Drug Administration (FDA), and upon successful completion, will satisfy the requirements for the filing of a 505(b)(2) New Drug Application (NDA). The Company expects to have topline data by year's end and to file the NDA in 2023.

- Entered into an agreement granting exclusive rights to develop, market and commercialize RENAZORB to Lee's Pharmaceutical (HK) Limited in Mainland China, Hong Kong, and certain other Asian markets. This agreement expands and accelerates the RENAZORB opportunity in one of the largest and most important markets for patients with hyperphosphatemia through a local partner with deep domain expertise. The Company received $1.0 million in an upfront fee and is eligible for royalties on sales and other milestone payments.

- Unicycive's strategy to bring the benefits of RENAZORB to patients around the world is to partner with market leaders in a variety of geographies outside of the U.S. Toward that end, the Company continues its discussions with potential partners in Asia and Europe. Unicycive has global intellectual property protection with over 40 granted and filed patents.

- Unicycive highlighted data supportive of RENAZORB's potential best-in-class profile for the treatment of hyperphosphatemia at the American Society of Nephrology's Kidney Week 2022 in a poster presentation titled, "Lanthanum Dioxycarbonate Effectively Reduces Urinary Phosphate Excretion in Healthy Volunteers" and in a published abstract titled, "Daily Medication Volume of Phosphate Binder Therapies." Those presentations can be accessed here.

*UNI-494*

UNI-494 is a novel proprietary drug targeting the SUR2B subunit of the mitochondrial $K_{ATP}$ channel that reduces oxidative stress and restores mitochondrial function. UNI-494 is cleaved by esterase enzymes to form nicorandil which is the active metabolite. Nicorandil has extensive safety and efficacy data from multiple clinical trials including a 5,000-patient randomized controlled trial (IONA Study) and there is a consensus in the literature that activation of the $K_{ATP}$ channel is the biological basis for the observed cardio-protection and reno-protection in multiple clinical trials.

In preclinical studies, UNI-494 showed improvement on the pharmacokinetic profile resulting in substantially higher exposure of nicorandil that may allow for less frequent and lower

dosing.

- Unicycive completed the non-clinical safety assessment studies required to initiate a Phase I study of UNI-494 in healthy volunteers.

- The Company's regulatory strategy is to initiate clinical development of UNI-494 in the United Kingdom (UK) to expedite clinical development. UNI-494 is metabolized to release nicorandil, a drug already approved and marketed in Europe with extensive safety data. Unicycive's analysis supports this strategy as the most cost-effective and expeditious path for the initial clinical development of UNI-494.

- Toward that end, the Company's plan is to file a Clinical Trial Application (CTA) to the Medicines and Healthcare Products Regulatory Agency (MHRA) in the UK to initiate a Phase I healthy volunteer study and expects to be cleared by the end of the year.

- In tandem, Unicycive plans to file an Investigational Drug Application (IND) with the FDA in early 2023 for a Phase I healthy volunteer study.

While Unicycive's initial focus is on acute kidney injury (AKI) and chronic kidney disease (CKD), UNI-494's novel mechanism of action may also hold promise for indications in which mitochondrial dysfunction is implicated such as liver disease (alcoholic hepatitis, hepatic encephalopathy) and ophthalmic disease (Dry Age-related Macular Degeneration, Glaucoma).

UNI-494 is protected by issued patents in the US and Europe with additional patent applications pending in other jurisdictions.

**Financial Results for Third Quarter Ended September 30, 2022**

- Licensing revenues for the third quarter ended September 30, 2022 were $1.0 million due to an agreement granting exclusive rights to develop, market and commercialize RENAZORB to Lee's Pharmaceutical (HK) Limited in Mainland China, Hong Kong, and certain other Asian markets. There was no comparable revenue in 2021.

- Research and development expenses for the third quarter ended September 30, 2022 were $4.8 million, compared with $3.8 million for the same period in 2021. This increase was primarily attributable to research progress and completion of several ongoing pre-clinical activities associated with the Company's RENAZORB and UNI-494 drug development programs.

- General and administrative expenses for the quarter ended September 30, 2022 were $1.7 million, compared with $0.9 million for the same quarter in 2021. This increase was primarily attributable to increased professional services and consulting expenses.

- Net loss for the three-month period ended September 30, 2022 was $5.6 million, or $0.37 per share of common stock, compared with a net loss of $5.2 million, or $0.37 per share of common stock, for the same three-month period in 2021.

- As of September 30, 2022, cash and cash equivalents totaled $7.0 million.

Fosrenol is a registered trademark of Shire Pharmaceutical Group plc (now Takeda

Pharmaceutical Company).

## -Tables to Follow-

**Unicycive Therapeutics, Inc.**

**Statements of Operations**
**(in thousands, except for share and per share amounts)**
**(Unaudited)**

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2021 | 2022 | 2021 | 2022 |
| Licensing revenues: | $ - | $ 951 | $ - | $ 951 |
| Operating expenses: | | | | |
| Research and development | 3,776 | 4,803 | 4,719 | 8,596 |
| General and administrative | 939 | 1,702 | 1,506 | 5,082 |
| Total operating expenses | 4,715 | 6,505 | 6,225 | 13,678 |
| Loss from operations | (4,715) | (5,554) | (6,225) | (12,727) |
| Other income (expenses): | | | | |
| Interest expense | (55) | (3) | (628) | (3) |
| Loss on debt conversion | (431) | - | (431) | - |
| Gain on extinguishment of debt | - | - | 19 | - |
| Total other income (expenses) | (486) | (3) | (1,040) | (3) |
| Net loss | $ (5,201) | $ (5,557) | $ (7,265) | $ (12,730) |
| Net loss per share, basic and diluted | $ (0.37) | $ (0.37) | $ (0.69) | $ (0.85) |
| Weighted-average shares outstanding used in computing net loss per share, basic and diluted | 14,167,098 | 15,061,995 | 10,538,473 | 15,050,389 |

**Unicycive Therapeutics, Inc.**
**Balance Sheets**
**(in thousands, except for share and per share amounts)**
**(Unaudited)**

| | As of December 31, 2021 | As of September 30, 2022 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash | $ 16,579 | $ 7,010 |
| Prepaid expenses and other current assets | 1,832 | 2,952 |
| Total current assets | 18,411 | 9,962 |
| Right of use asset, net | 305 | 191 |
| Property, plant and equipment, net | 28 | 24 |
| Total assets | $ 18,744 | $ 10,177 |
| **Liabilities and stockholders' (deficit) equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 742 | $ 2,292 |
| Accrued liabilities | 1,212 | 3,065 |
| Operating lease liability - current | 151 | 165 |
| Total current liabilities | 2,105 | 5,522 |
| Operating lease liability - long term | 155 | 29 |
| Total liabilities | 2,260 | 5,551 |
| Commitments and contingencies | | |
| Stockholders' (deficit) equity: | | |

| | | |
|---|---|---|
| Preferred stock: $0.001 par value per share—10,000,000 shares authorized at December 31, 2021 and September 30, 2022; no shares issued and outstanding at December 31, 2021 and September 30, 2022 | $ - | $ - |
| Common stock, $0.001 par value per share – 200,000,000 shares authorized at December 31, 2021 and September 30, 2022; 14,996,534 shares issued and outstanding at December 31, 2021, and 15,087,943 shares issued and outstanding at September 30, 2022 | 15 | 15 |
| Additional paid-in capital | 32,408 | 33,280 |
| Accumulated deficit | (15,939) | (28,669) |
| Total stockholders' (deficit) equity | 16,484 | 4,626 |
| Total liabilities and stockholders' (deficit) equity | $ 18,744 | $ 10,177 |

## About Unicycive Therapeutics

Unicycive Therapeutics is a biotechnology company developing novel treatments for kidney diseases. Unicycive's lead drug, RENAZORB (lanthanum dioxycarbonate), is a novel investigational 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 statement

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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