August 14, 2023

# Unicycive Announces Second Quarter 2023 Financial Results and Provides Business Update

*Recent Data Publications Highlight the Benefits of Oxylanthanum Carbonate (OLC) to Improve Medication Adherence and Quality of Life for Patients with Chronic Kidney Disease*

*Feedback from FDA Expected in Fall 2023 for OLC Program*

*UNI-494 Phase 1 Trial Progressing as Planned with IND Application Expected in 2024*

LOS ALTOS, Calif., Aug. 14, 2023 (GLOBE NEWSWIRE) -- Unicycive Therapeutics, Inc. (Nasdaq: UNCY) (the "Company" or "Unicycive"), a clinical-stage biotechnology company developing therapies for patients with kidney disease, today announced its financial results for the second quarter ended June 30, 2023, and provided a business update.

"Data publications and presentations continue to highlight the benefits of both our lead asset, Oxylanthanum Carbonate (OLC), and UNI-494 targeting treatment for patients with life threatening kidney diseases," said Shalabh Gupta, M.D., Chief Executive Officer of Unicycive. "For OLC, we expect to gain alignment with the U.S. Food and Drug Administration in the Fall of this year around the additional data requirements to advance the program towards submission of a New Drug Application. As we reported last month, recently published data demonstrated that OLC has the potential to improve medication adherence and the quality of life for patients suffering from chronic kidney disease. This reinforces our commitment to bring this important new treatment option to patients as soon as possible."

"Preclinical data from UNI-494 presented this quarter highlighted its novel mechanism of action to restore mitochondrial function. Importantly, the data showed UNI-494 was well tolerated and may protect the kidney against harmful effects related to acute kidney injury, a condition for which there are currently no approved treatments. Our Phase 1 study is ongoing in the United Kingdom, and as we reported previously, we are continuing with the healthy volunteer dosing. Concurrently, we plan to request a pre-IND meeting with the FDA before the end of this year to prepare to conduct further clinical studies in the U.S. in 2024," concluded Dr. Gupta.

**Key Highlights**

- The *American Journal of Nephrology* published positive results on the phosphate binding capacity for OLC showing that OLC had the lowest daily phosphate binder dose volume and the lowest volume required to bind one gram of phosphate compared to five other commercially available phosphate binders.

- Presented preclinical data highlighting the potential safety and suggestive efficacy of UNI-494 in oral presentations at the 60th European Renal Association Congress (ERA 2023).

- Adopted the non-proprietary name, oxylanthanum carbonate (OLC) by the United States Adopted Name (USAN) organization, replacing lanthanum dioxycarbonate (LDC).

**Financial Results for the Second Quarter Ended June 30, 2023**

Research and Development (R&D) Expenses: R&D expenses for the quarter ended June 30, 2023 were $2.3 million, compared to $1.9 million for the same period in 2022. This increase was primarily attributable to an increase in development costs of $0.3 million for product formulation, clinical study, and preclinical study services in the current period. Labor, consulting, and other costs increased $0.1 million.

General and Administrative (G&A) Expenses: G&A for the quarter ended June 30, 2023 were $2.1 million, compared to $1.8 million for the same quarter of 2022. This increase was primarily attributable to an increase of $0.5 million in consulting and professional services costs. Non-cash stock compensation costs decreased $0.1 million, Insurance expense for directors and officers decreased $0.2 million, and labor, rent, travel, supplies and other costs increased $0.1 million.

Other Income (Expenses): Other income (expenses) for the quarter ended June 30, 2023 increased $0.5 million due primarily to the revaluation of the warrant liability.

Net Loss: Net loss attributable to common stockholders for the quarter ended June 30, 2023 was $4.4 million, or $0.29 per share of common stock, compared to a net loss of $3.6 million, or $0.24 per share of common stock, for the same three-month period in 2022. This decrease was attributable primarily to a $0.3 million increase in drug development costs.

Cash Position: As of June 30, 2023, cash and cash equivalents totaled $18.8 million.

**About Oxylanthanum Carbonate (OLC)**

Oxylanthanum carbonate is a 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). OLC has over forty issued and granted patents globally. Its potential best-in-class profile may have meaningful patient adherence benefits over currently available treatment options as it requires a lower pill burden for patients in terms of number and size of pills per dose that are swallowed instead of chewed. Based on a survey conducted in 2022, Nephrologists stated that the greatest unmet need in the treatment of hyperphosphatemia with phosphate binders is a lower pill burden and better patient compliance.[1] The global market opportunity for treating hyperphosphatemia is projected to be in excess of $2.5 billion in 2023, with the United States accounting for more than $1 billion of that total. Despite the availability of several FDA-cleared medications, 75 percent of U.S. dialysis patients fail to achieve the target phosphorus levels recommended by published medical guidelines.

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

the clinical development program, two clinical studies were conducted in over 100 healthy volunteers. The first study was a dose-ranging Phase I study to determine safety and tolerability. The second study was a randomized, open-label, two-way crossover bioequivalence study to establish pharmacodynamic bioequivalence between OLC and Fosrenol. Based on the topline results of the bioequivalence study, pharmacodynamic (PD) bioequivalence of OLC to Fosrenol was established.

Fosrenol® is a registered trademark of Shire International Licensing BV.
[1]Reason Research, LLC 2022 survey. Results here.

**About UNI-494**

UNI-494 is a novel patent-protected drug that selectively binds to the SUR2B subunit of the mitochondrial $K_{ATP}$ channel and activates it to restore mitochondrial function and reduce oxidative stress. The totality of the data presented so far this year, underscore UNI-494's potential to be safe, reno-protective, and to have low risk of drug-drug interactions, all of which are important findings for this product candidate as a promising therapeutic for acute kidney injury, a condition for which there are currently no FDA approved therapies.

**About Unicycive Therapeutics**

Unicycive Therapeutics is a biotechnology company developing novel treatments for kidney diseases. Unicycive's lead drug candidate, oxylanthanum carbonate (OLC), is a novel investigational phosphate binding agent being developed for the treatment of hyperphosphatemia in chronic kidney disease patients on dialysis. 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 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 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, 2022, 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.

**Unicycive Therapeutics, Inc.**

**Balance Sheets**
**(in thousands, except for share and per share amounts)**

| | As of December 31, 2022 | As of June 30, 2023 (Unaudited) |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash | $ 455 | $ 18,818 |
| Prepaid expenses and other current assets | 2,189 | 3,112 |
| Total current assets | 2,644 | 21,930 |
| Right of use asset, net | 152 | 923 |
| Property, plant and equipment, net | 22 | 30 |
| Total assets | $ 2,818 | $ 22,883 |
| **Liabilities and stockholders' (deficit) equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 892 | $ 503 |
| Accrued liabilities | 2,237 | 1,689 |
| Warrant liability | - | 12,924 |
| Operating lease liability - current | 155 | 303 |
| Total current liabilities | 3,284 | 15,419 |
| Operating lease liability - long term | - | 634 |
| Total liabilities | 3,284 | 16,053 |
| Commitments and contingencies | | |
| Mezzanine equity: | | |
| Series A-1 preferred stock, $0.001 par value per share–zero and 30,190 shares authorized at December 31, 2022 and June 30, 2023, respectively; zero and 30,190 shares issued and outstanding, liquidation preference of zero and $31.0 million at December 31, 2022, and June 30, 2023, respectively | - | 26,202 |
| Stockholders' deficit: | | |
| Preferred stock, $0.001 par value per share – 10,000,000 and 9,969,810 shares authorized at December 31, 2022 and June 30, 2023, respectively; no shares issued and outstanding at December 31, 2022, and June 30, 2023 | $ - | $ - |
| Common stock, $0.001 par value per share – 200,000,000 shares authorized at December 31, 2022 and March 31, 2023; 15,231,655 shares issued and outstanding at December 31, 2022, and 15,236,016 shares issued and outstanding at June 30, 2023 | 15 | 15 |
| Additional paid-in capital | 33,516 | 33,023 |
| Accumulated deficit | (33,997) | (52,410) |
| Total stockholders' deficit | (466) | (19,372) |
| Total liabilities, mezzanine equity, and stockholders' deficit | $ 2,818 | $ 22,883 |

**Unicycive Therapeutics, Inc.**

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

| | Three Months Ended June 30, 2022 | Three Months Ended June 30, 2023 |
|---|---|---|
| Licensing revenues: | $ - | $ - |
| Operating expenses: | | |
| Research and development | 1,860 | 2,267 |
| General and administrative | 1,776 | 2,055 |
| Total operating expenses | 3,636 | 4,322 |
| Loss from operations | (3,636) | (4,322) |
| Other income (expenses): | | |
| Interest income | - | 234 |
| Interest expense | - | (32) |
| Change in fair value of warrant liability | - | 282 |
| Total other income (expenses) | - | 484 |
| Net loss | $ (3,636) | $ (3,838) |
| Deemed dividend to Series A-1 preferred stockholders | - | (603) |
| Net loss attributable to common stockholders | $ (3,636) | $ (4,441) |
| Net loss per share attributable to common stockholders, basic and diluted | $ (0.24) | $ (0.29) |
| Weighted-average shares outstanding used in computing net loss per share, basic and diluted | 15,028,689 | 15,234,570 |

Source: Unicycive Therapeutics, Inc.