May 12, 2022

Unicycive Announces First Quarter Financial Results and Provides Business Update

On track to initiate clinical bioequivalence study of Renazorb to treat hyperphosphatemia in healthy volunteers in second quarter 2022

Plans to initiate Phase 1 study for UNI-494 in second half of 2022

LOS ALTOS, Calif., May 12, 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 first quarter ended March 31, 2022 and provided a business update.

Management Commentary

“Throughout the first quarter, we continued to make meaningful progress to advance and expand the clinical development of our lead product candidates. We are on track to start our pivotal bioequivalence trial of Renazorb this quarter, which will form the basis of our 505(b)(2) New Drug Application (NDA) filing. We are also looking forward to announcing new pre-clinical data and to initiating the first-in-humans clinical program for UNI-494, our drug that is focused on mitochondrial biology, in the second half of the year,” said Shalabh Gupta, M.D., Chief Executive Officer. “We are adequately funded into 2023, which is expected to allow us to file our NDA for Renazorb and to conduct the clinical trial for UNI-494. Moving forward, we have an exciting year ahead and are confident in our talented and dedicated team’s ability to execute our strategy to achieve our ambitious goals to bring these innovative new treatments to patients.”

Program Updates

Renazorb (lanthanum dioxycarbonate)

Renazorb 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). 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.

- Unicycive plans to enroll the first subject in a bioequivalence (BE) study in healthy volunteers to demonstrate the comparability of Renazorb to the reference listed drug, Fosrenol, in the second quarter. The design for the BE study has been agreed upon by FDA, and upon successful completion, will satisfy the requirements for the filing of a 505(b)(2) NDA.

- A market research study of 100 US nephrologists commissioned in the first quarter indicated a strong prescribing preference for Renazorb's potential best-in-class product profile over other currently available phosphate binders.

- 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 has initiated discussions with potential partners in Asia and Europe. Unicycive has global intellectual property protection with over 40 granted and filed patents.

- Unicycive announced acceptance of a poster and oral presentations of Renazorb preclinical studies at the upcoming European Renal Association Congress taking place May 19-22, 2022 in Paris, France.

- The Company supported a Key Opinion Leader Event hosted by covering analyst, Elemer Piros, Ph.D., senior biotechnology analyst at ROTH Capital, which featured Glenn Chertow, M.D., MPH, Professor of Medicine at Stanford University School of Medicine and, by courtesy, Professor of Epidemiology and Population Health and discussed the great unmet need in hyperphosphatemia and the significant potential for an effective, new treatment such as Renazorb. The event can be viewed here.

UNI-494

UNI-494 is a new chemical entity in late preclinical development with a novel mechanism of action that targets mitochondria. Mitochondrial dysfunction is implicated in acute and chronic disease pathologies in organ systems with high energy demands like the heart, kidney, liver, and eye. While Unicycive's initial focus is on acute kidney injury (AKI), UNI-494's novel mitochondrial mechanism may also hold promise for indications beyond the kidney.

- Unicycive completed chemical synthesis for animal studies and initiated preclinical *in vivo* studies to support an IND submission expected in the second half of 2022.

- Company plans to initiate a first-in-humans Phase 1 study of UNI-494 in the second half of 2022.

Financial Results for First Quarter Ended 2022

- Research and development expenses for the first quarter ended March 31, 2022 were $1.9 million, compared to $0.5 million for the same period in 2021. This increase was primarily attributable to increased costs associated with the Company's Renazorb and UN1-494 drug development programs.

- General and administrative expenses for the quarter ended March 31, 2022 were $1.6 million, compared to $0.3 million for the same quarter in 2021. This increase was primarily attributable to costs associated with increased officer and insurance as well as increased professional services and consulting expenses.

- Net loss for the three-month period ended March 31, 2022 was $3.5 million, or $0.24 per share of common stock, compared to a net loss of $1.0 million, or $0.11 per share

of common stock, for the same three-month period in 2021.

- As of March 31, 2022, cash and cash equivalents totaled $13.6 million, which the Company believes is sufficient to support it through to several milestones, including the completion of the NDA submission for Renazorb and clinical trial for UNI-494.

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.

Investor Contact:

ir@unicycive.com
(650) 900-5470

Anne Marie Fields
Stern Investor Relations
annemarie.fields@sternir.com
212-362-1200

SOURCE: Unicycive Therapeutics, Inc.

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Unicycive Therapeutics, Inc.

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

	As of December 31, 2021	As of March 31, 2022
Assets		
Current assets:		
Cash	$ 16,579	$ 13,620
Prepaid expenses and other current assets	1,832	1,844
Total current assets	18,411	15,464
Right of use asset, net	305	268
Property, plant and equipment, net	28	28
Total assets	$ 18,744	$ 15,760
Liabilities and stockholders' (deficit) equity		
Current liabilities:		
Accounts payable	$ 742	$ 589
Accrued liabilities	1,212	1,658
Operating lease liability - current	151	155
Total current liabilities	2,105	2,402
Operating lease liability - long term	155	114

Total liabilities	2,260	2,516
Commitments and contingencies		
Stockholders' (deficit) equity:		
Preferred stock: $0.001 par value per share—10,000,000 shares authorized at December 31, 2021 and March 31, 2022; no shares issued and outstanding at December 31, 2020 and March 31, 2021	$ -	$ -
Common stock, $0.001 par value per share – 200,000,000 shares authorized at December 31, 2021 and March 31, 2022; 14,996,534 shares issued and outstanding at December 31, 2021, and 15,020,517 shares issued and outstanding at March 31, 2022	15	15
Additional paid-in capital	32,408	32,705
Accumulated deficit	(15,939)	(19,476)
Total stockholders' (deficit) equity	16,484	13,244
Total liabilities and stockholders' (deficit) equity	$ 18,744	$ 15,760

Unicycive Therapeutics, Inc.

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

	Three Months Ended March 31,	
	2021	**2022**
Operating expenses:		
Research and development	$ 450	$ 1,933
General and administrative	281	1,604
Total operating expenses	731	3,537
Loss from operations	(731)	(3,537)
Other expenses:		
Interest expense	(252)	-
Gain on extinguishment of debt	19	-
Total other expenses	(233)	-
Net loss	$ (964)	$ (3,537)
Net loss per share, basic and diluted	$ (0.11)	$ (0.24)
Weighted-average shares outstanding used in computing net loss per share, basic and diluted	8,576,422	15,004,617

Source: Unicycive Therapeutics, Inc.