March 31, 2022

Unicycive Announces Full Year 2021 Financial Results and Provides Business Update

On track to initiate clinical bioequivalence study of Renazorb to treat hyperphosphatemia in healthy volunteers in first half of 2022

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

LOS ALTOS, Calif., March 31, 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 full year ended December 31, 2021 and provided a business update.

“The considerable progress we made throughout 2021 puts us in a strong position to execute on our strategy to advance our clinical development programs to address two important renal diseases where current treatment options are suboptimal,” said Shalabh Gupta, M.D., Chief Executive Officer. “Central to our progress was the confirmatory regulatory guidance we received from the U.S. Food and Drug Administration (FDA) regarding the path to marketing approval for our lead product candidate, Renazorb. We are delighted the FDA affirmed its guidance to enable us to pursue the 505(b)2 regulatory pathway, which we believe will significantly reduce the clinical timelines and expense for bringing this enhanced hyperphosphatemia therapy to chronic kidney disease patients seeking new treatment options for this continually challenging condition.

"We have an exciting year ahead at Unicycive as we advance our late-stage program in hyperphosphatemia, initiate first-in-human studies of our earlier stage program with UNI-494 in Acute Kidney Injury and strive to achieve a number of potentially value-creating milestones,” concluded Dr. Gupta.

Recent Highlights

- Received additional confirmatory guidance on the regulatory pathway for Renazorb (lanthanum dioxycarbonate) from the FDA following a Type C meeting in early March in which the FDA confirmed previous guidance that Unicycive may support the New Drug Application (NDA) filing of Renazorb through a 505(b)(2) pathway based on a single clinical bioequivalence (BE) study in healthy volunteers, along with the previously agreed-upon 6-month mouse toxicology study.
- An agreement was reached with the FDA on the clinical study design including the dose of Renazorb and Fosrenol, sample size and the primary endpoints of the bioequivalence study. The primary endpoint of the study is LS mean change in urinary phosphate excretion from baseline to the evaluation period.
- Based on this guidance, the Company has selected an experienced Clinical Research

Organization (CRO) based in North America for the conduct of the healthy volunteer BE study which is expected to enroll its first patient in the second quarter of this year.
- Announced the acceptance of two abstracts supporting the potential efficacy and safety of Renazorb to be presented as posters at the National Kidney Foundation (NKF) Spring Clinical Meeting taking place April 6-10, 2022, in Boston.
- Announced acceptance of poster and oral presentations of Renazorb preclinical studies at the European Renal Association Congress taking place May 19-22, 2022 in Paris, France and virtually.
- Selected a clinical CRO to start the Phase I study for UNI-494, which is targeted to be initiated in the second half of 2022.
- Unicycive rang the NASDAQ Closing Bell on March 29, 2022 in commemoration of National Kidney Month and the Company's commitment to developing medicines for patients suffering from this serious disease.

Clinical Programs

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 is preparing a clinical bioequivalence study to be performed in healthy volunteers in order to submit a 505(b)(2) NDA to the FDA. The Company is making ongoing progress with this program and has submitted the BE study protocol to the FDA. Unicycive has selected a CRO that will conduct the BE study and remains on track to initiate this study in the second quarter of 2022, with a goal to complete the study by the end of 2022.

The Company identified a preclinical CRO and initiated the work for the 6-month toxicology study that is required for the submission of the Renazorb NDA and this study remains on track to be completed in time for NDA submission.

Unicycive is looking forward to the presentation of preclinical and clinical data at the National Kidney Foundation Spring Meeting that support the potential safety and efficacy of Renazorb to treat hyperphosphatemia in chronic kidney disease patients.

The hyperphosphatemia treatment market exceeds one billion dollars in the U.S. and more than double that in the rest of the world. The Unicycive team is preparing to capitalize on this substantial opportunity by offering patients and providers an attractive treatment alternative. In tandem with the clinical development program, the Company is focused on its commercialization plans for Renazorb in the U.S. and around the world. Unicycive is conducting important market research to inform its brand and market access strategy and comprehensive launch plan for Renazorb.

UNI-494

UNI-494 is a patent-protected new chemical entity in late preclinical development for the

treatment of acute kidney injury.

Unicycive continues to make progress toward advancing UNI-494 into the clinic and, toward that end, has completed chemical synthesis for animal studies and has initiated preclinical *in vivo* studies to support an Investigational New Drug submission expected in mid-2022. The Company plans to initiate a first-in-humans Phase 1 study of UNI-494 in the third quarter of 2022.

Financial Results for the Year Ended December 31, 2021

Research and development expenses for the full year ended December 31, 2021 were $6.1 million, compared to $1.0 million for the same period in 2020. This increase was primarily attributable to a one-time $2.2 million increase in non-cash expense from the issuance of common stock to our Renazorb licensor. Development costs increased $1.4 million from the prior year.

General and administrative expenses for the fiscal year ended 2021 were $2.9 million, compared to $1.0 million for the year ended 2020. This increase was primarily attributable to an increase of $0.7 million in insurance expense for directors and officers.

Net loss for the 12-month period ended December 31, 2021 was $10.0 million, or $0.86 per share of common stock, compared to a net loss of $2.3 million, or $0.27 per share of common stock, for the same 12-month period in 2020. This increase was primarily attributable to non-cash stock issuance expense in the current period.

As of December 31, 2021, cash and cash equivalents totaled $16.6 million.

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

SOURCE: Unicycive Therapeutics, Inc.

-Tables to Follow-

Unicycive Therapeutics, Inc.

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

	As of December 31, 2020	As of December 31, 2021
Assets		
Current assets:		
Cash	$ -	$ 16,579
Deferred offering costs	200	-
Prepaid expenses and other current assets	4	1,832
Total current assets	204	18,411
Right of use asset, net	-	305
Property, plant and equipment, net	-	28
Total assets	$ 204	$ 18,744
Liabilities and stockholders' (deficit) equity		
Current liabilities:		
Accounts payable	$ 184	$ 742
Related party service fee payable	9	-
Accrued liabilities	168	1,212
Convertible notes	1,528	-
Loan from stockholder	967	-
Operating lease liability - current	-	151
Government loan	19	-
Total current liabilities	2,875	2,105
Operating lease liability - long term	-	155
Total liabilities	2,875	2,260
Commitments and contingencies		
Stockholders' (deficit) equity:		
Preferred stock: $0.001 par value per share—10,000,000 shares authorized at December 31, 2020 and 2021; no shares issued and outstanding at December 31, 2020 and 2021	$ -	$ -
Common stock, $0.001 par value per share – 200,000,000 shares authorized at December 31, 2020 and 2021; 8,514,070 shares issued and outstanding at December 31, 2020, and 14,966,534 shares issued and outstanding at December 31, 2021	9	15
Additional paid-in capital	3,242	32,408
Accumulated deficit	(5,922)	(15,939)
Total stockholders' (deficit) equity	(2,671)	16,484
Total liabilities and stockholders' (deficit) equity	$ 204	$ 18,744

Unicycive Therapeutics, Inc.

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

	Year Ended December 31, 2020	Year Ended December 31, 2021
Operating expenses:		
Research and development	$ 1,015	$ 6,080

General and administrative	1,005	2,897
Total operating expenses	2,020	8,977
Loss from operations	(2,020)	(8,977)
Other expenses:		
Interest expense	(244)	(628)
Loss on debt conversion	-	(431)
Gain on extinguishment of debt	-	19
Total other expenses	(244)	(1,040)
Net loss	$ (2,264)	$ (10,017)
Net loss per share, basic and diluted	$ (0.27)	$ (0.86)
Weighted-average shares outstanding used in computing net loss per share, basic and diluted	8,499,687	11,675,750

Source: Unicycive Therapeutics, Inc.