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): **August 15, 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 2.02 Results of Operations and Financial Conditions.

On August 15, 2022, Unicycive Therapeutics, Inc. issued a press release announcing company highlights and financial results for the three months ended June 30, 2022. A copy of the press release is furnished as Exhibit 99.1 to this Form 8-K.

The information disclosed under this Item 2.02, including Exhibit 99.1 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 August 15, 2022.
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: August 15, 2022

UNICYCIVE THERAPEUTICS, INC.

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

Press Release

Unicycive Announces Second Quarter Financial Results and Provides Business Update

Advancing global commercial strategy for Renazorb to treat hyperphosphatemia

On track to file regulatory submission to initiate Phase 1 healthy volunteer study with UNI-494 in second half of 2022

LOS ALTOS, Calif., August 15, 2022 -- Unicycive Therapeutics, Inc. (Nasdaq: UNCY), a clinical stage biotechnology company developing therapies for patients with kidney disease, today announced its financial results for the second quarter ended June 30, 2022 and provided a business update.

Management Commentary

"We made considerable progress executing our strategy throughout the first half of the year. Toward that end, we were delighted to initiate our pivotal bioequivalence trial of Renazorb®, which keeps us on track to complete the study around yearend and to file a New Drug Application (NDA) in 2023. In addition, we signed our first global partnership for the marketing and commercialization of Renazorb in China with Lee's Pharmaceutical (HK) Limited. This agreement provides Unicycive with non-dilutive funding, including a $1.0 million upfront payment received in August, which underscores the potential for Renazorb as a best-in-class phosphate binder worldwide."

"We continue to develop and build compelling scientific knowledge in support of UNI-494's unique mechanism of action to restore mitochondrial function in a variety of diseases that are affected by mitochondrial dysfunction and look forward to regulatory filing to initiate the first-in-humans clinical program for UNI-494 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 advance Renazorb to NDA filing and to initiate the clinical trial for UNI-494. We continue to execute according to our plan and remain excited about the opportunities ahead for Unicycive as we advance our clinical studies, expand access to Renazorb around the world and further elucidate the potential of UNI-494's novel mechanism for the improvement of 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 (lanthanum dioxycarbonate) 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.

- During the second quarter, Unicycive initiated a 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 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) NDA.

- 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 who has deep domain expertise. The Company received $1.0 million in upfront fees and is eligible for royalties on sales and other milestone payments.

- Reported results from a market research study of 100 U.S. nephrologists that estimated that they will prescribe Renazorb (pending FDA approval) for a market-leading 34% of their dialysis patients requiring phosphate binder therapy. Nephrologists stated that the greatest unmet need in the treatment of hyperphosphatemia with phosphate binders is lower pill burden and better patient compliance.

- Announced key findings from independent Renal Dietitian survey that ranked hyperphosphatemia as the area of greatest unmet need in their kidney disease patients and indicated a high level of interest in the Renazorb product profile given it appealing benefits of efficacy/potency and lower pill burden. Renal dietitians also report that their highest degree of influence is on phosphate binder choice compared with other drug categories.

- 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 presented preclinical data in support of Renazorb's first-in-class potential in a poster and oral presentations at the European Renal Association Congress that took place in May in Paris. Those presentations can be accessed here.

UNI-494

UNI-494 is a mitochondrial K_{ATP} channel opener 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 5000-patient randomized controlled trial (IONA Study) and there is a consensus in the literature that the activation of 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 pharmacokinetic, safety pharmacology, genetic toxicity and ADME studies. Repeat dose toxicity studies in two species are on track to be completed in the third quarter. The Company is on track to file a regulatory submission to initiate the Phase I healthy volunteer study in the second half of 2022.

While Unicycive's initial focus is on acute kidney injury (AKI), UNI-494's novel mechanism of action may also hold promise for indications in which mitochondrial dysfunction is implicated such as chronic kidney disease, liver disease (alcoholic hepatitis, hepatic encephalopathy) and ophthalmic disease (dry AMD, macular degeneration etc).

UNI-494 is patent protected by issued patent(s) in the US and Europe and a wide range patent applications worldwide.

Financial Results for Second Quarter Ended 2022

- Research and development expenses for the second quarter ended June 30, 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 June 30, 2022 were $1.8 million, compared to $0.3 million for the same quarter in 2021. This increase was primarily attributable to costs associated with increased director and officer insurance as well as increased professional services and consulting expenses.
- Net loss for the three-month period ended June 30, 2022 was $3.6 million, or $0.24 per share of common stock, compared to a net loss of $1.1 million, or $0.13 per share of common stock, for the same three-month period in 2021.
- As June 30, 2022, cash and cash equivalents totaled $10.6 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.

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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SOURCE: Unicycive Therapeutics, Inc.

-Tables to Follow-

Unicycive Therapeutics, Inc.

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

	As of December 31, 2021	As of June 30, 2022
Assets		
Current assets:		
Cash	$ 16,579	$ $10,573
Prepaid expenses and other current assets	1,832	1,987
Total current assets	18,411	12,560
Right of use asset, net	305	230
Property, plant and equipment, net	28	26
Total assets	$ 18,744	$ 12,816
Liabilities and stockholders' (deficit) equity		
Current liabilities:		

Accounts payable	$ 742	$ 747
Accrued liabilities	1,212	1,927
Operating lease liability – current	151	160
Total current liabilities	2,105	2,834
Operating lease liability – long term	155	72
Total liabilities	2,260	2,906
Commitments and contingencies (Note 8)		
Stockholders' (deficit) equity:		
Preferred stock: $0.001 par value per share—10,000,000 shares authorized at December 31, 2021 and June 30, 2022; no shares issued and outstanding at December 31, 2021 and June 30, 2022	$ -	$ -
Common stock, $0.001 par value per share – 200,000,000 shares authorized at December 31, 2021 and June 30, 2022; 14,996,534 shares issued and outstanding at December 31, 2021, and 15,044,498 shares issued and outstanding at June 30, 2022	15	15
Additional paid-in capital	32,408	33,007
Accumulated deficit	(15,939)	(23,112)
Total stockholders' (deficit) equity	16,484	9,910
Total liabilities and stockholders' (deficit) equity	$ 18,744	$ 12,816

Unicycive Therapeutics, Inc.

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

	Three Months Ended June 30,		Six. Months Ended June 30,	
	2021	2022	2021	2022
Operating expenses:				
Research and development	$ 493	$ 1,860	$ 942	$ 3,793
General and administrative	286	1,776	568	3,380
Total operating expenses	779	3,636	1,510	7,173
Loss from operations	(779)	(3,636)	(1,510)	(7,173)
Other expenses:				
Interest expense	(321)	-	(573)	-
Gain on extinguishment of debt	-	-	19	-
Total other expenses	(321)	-	(554)	
Net loss	$ (1,100)	$ (3,636)	$ (2,064)	$ (7,173)
Net loss per share, basic and diluted	$ (0.13)	$ (0.24)	$ (0.24)	$ (0.48)
Weighted-average shares outstanding used in computing net loss per share, basic and diluted	8,771,290	15,028,689	8,677,497	15,024,581