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): **May 16, 2023**

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 May 16, 2023, Unicycive Therapeutics, Inc. issued a press release announcing its financial results for the first quarter ended March 31, 2023 and provided a business update. 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 May 16, 2023.
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: May 16, 2023

UNICYCIVE THERAPEUTICS, INC.

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

Unicycive Announces First Quarter 2023 Financial Results and Provides Business Update

Closed on previously announced transformational fundraising that included $30 million financing upfront with up to an additional $100 million tied to the satisfaction of milestones

Continued progress with plan to file New Drug Application with the U.S. Food and Drug Administration in Q3 2023, with the potential for approval and launch in 2024

LOS ALTOS, Calif., May 16, 2023 -- 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 first quarter ended March 31, 2023 and provided a business update.

"The first quarter of 2023 was transformational for Unicycive and positions us for continued success throughout the balance of the year and beyond as we expect to file our New Drug Application (NDA) for Renazorb™ in the third quarter of 2023 and, if approved, plan for its potential commercial launch in 2024, which should provide additional funding in connection with our recent financing agreement," said Shalabh Gupta, M.D., Chief Executive Officer of Unicycive.

"Additionally, we continue to expand our scientific and clinical body of evidence for both of our product candidates' potential to transform the treatment of acute and chronic kidney disease. The Unicycive team has presented data from studies of Renazorb and UNI-494 at key renal medical meetings worldwide. We will continue to share data demonstrating the potential of our lead programs in kidney disease before audiences of the world's leading nephrologists and believe it may enhance our commercial launch efforts for Renazorb and our development efforts as we advance our global clinical trials for UNI-494," concluded Dr. Gupta.

Key Highlights of the First Quarter and Recent Months

- In February 2023, Unicycive entered into an exclusive license agreement with Lotus Pharmaceutical ("Lotus", Taiwan TWSE ticker: 1795), a leading global pharmaceutical company, for the development and commercialization of Renazorb (lanthanum dioxycarbonate) in the Republic of Korea.
- In early March 2023, the Company signed a securities purchase agreement with certain healthcare-focused institutional investors that provides for up to $130 million in gross proceeds through a private placement that included initial upfront funding of $30 million with additional capital available to the Company at increasing share prices upon achievement of milestones with mandated dividends to shareholders as the Company generates cash profits.

- Presented data from clinical studies on Renazorb and pre-clinical studies on UNI-494 in multiple conferences globally.
- Unicycive first-in-human Phase 1 study of UNI-494 in healthy volunteers in the United Kingdom has completed enrollment of its first cohort. Following the completion of this Phase 1 study, the Company plans to file a corresponding Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA) in 2024 for a Phase 2 trial in AKI patients.
- This summer, the Company is presenting preclinical data highlighting the safety and suggestive efficacy of UNI-494 in oral presentations at the 60th European Renal Association Congress (ERA 2023) taking place in Milan, Italy from June 15-18, 2023.

Financial Results for the First Quarter Ended March 31, 2023

Licensing revenues were $0.7 million for the quarter ended March 31, 2023 due to a licensing agreement executed in February 2023.

Research and development expenses for the quarter ended March 31, 2023 were $3.0 million, compared to $1.9 million for the same period in 2022. This increase was primarily attributable to development costs of $1.0 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 expenses for the quarter ended March 31, 2023 were $1.8 million, compared to $1.6 million for the same quarter of 2022. This increase was primarily attributable to an increase of $0.4 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 rent, travel, supplies and other costs increased $0.1 million.

Net loss for the three-month period ended March 31, 2023 was $14.6 million, or $0.97 per share of common stock, compared to a net loss of $3.5 million, or $0.24 per share of common stock, for the same three-month period in 2022. This increase was attributable to increased development costs as well as the $10.4 million change in fair value of warrant liability.

As of March 31, 2023, cash and cash equivalents totaled $24.3 million compared with $0.5 million in cash and cash equivalents held at December 31, 2022. Following the close of the fourth quarter ended December 31, 2022, the Company completed a securities purchase agreement with certain healthcare-focused institutional investors that will provide up to $130.0 million in gross proceeds through a private placement and that included initial upfront funding of $30.0 million.

About Renazorb (lanthanum dioxycarbonate)

Renazorb is an investigational phosphate binding agent utilizing proprietary nanoparticle technology being developed for the treatment of hyperphosphatemia in patients with chronic kidney disease (CKD) on dialysis. Renazorb 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 smaller and fewer number of pills per dose and is swallowed instead of chewed. The timing of Renazorb's expected launch coincides favorably with the pending expansion of Medicare patient access to phosphate binders in 2025 when these products are added to the end stage renal disease (ESRD) PPS through the Center for Medicare and Medicaid's Transitional Drug Add-On Payment Adjustment ("TDAPA") program. 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

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 AKI, a condition for which there are currently no FDA approved therapies.

About Unicycive Therapeutics

Unicycive is focused on two kidney diseases with large unmet medical needs. We are developing Renazorb, an investigational phosphate binding agent using proprietary nanoparticle technology for the treatment of patients with hyperphosphatemia. We plan to file a New Drug Application (NDA) for Renazorb with the U.S. Food and Drug Administration (FDA) mid-year. We are also developing UNI-494, a new chemical entity with a novel mechanism of action that restores mitochondrial function in acute and chronic diseases. Our initial target for UNI-494 is acute kidney injury (AKI), for which there are currently no FDA-approved medicines. For more information, please visit www.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, 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, 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.

Investor Contact:

ir@unicycive.com
(650) 900-5470

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

--Tables to Follow—

Unicycive Therapeutics, Inc.

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

	As of December 31, 2022	As of March 31, 2023 (Unaudited)
Assets		
Current assets:		
Cash and cash equivalents	$ 455	$ 24,332
Prepaid expenses and other current assets	2,189	1,852
Total current assets	2,644	26,184
Right of use asset, net	152	997
Property, plant and equipment, net	22	21
Total assets	$ 2,818	$ 27,202
Liabilities, mezzanine equity, and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 892	$ 790
Accrued liabilities	2,237	1,698
Warrant liability	-	13,206
Operating lease liability - current	155	276
Total current liabilities	3,284	15,970
Operating lease liability – long term	-	715
Total liabilities	3,284	16,685
Commitments and contingencies (Note 8)		
Mezzanine equity:		

Series A-1 preferred stock, $0.001 par value per share–zero and 30,190 shares authorized at December 31, 2022 and March 31, 2023, respectively; zero and 30,190 shares issued and outstanding, liquidation preference of zero and $30.6 million at December 31, 2022, and March 31, 2023, respectively	-	25,599
Stockholders' deficit:		
Preferred stock, $0.001 par value per share – 10,000,000 and 9,969,810 shares authorized at December 31, 2022 and March 31, 2023, respectively; no shares issued and outstanding at December 31, 2022, and March 31, 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 15,233,836 shares issued and outstanding at March 31, 2023	15	15
Additional paid-in capital	33,516	33,475
Accumulated deficit	(33,997)	(48,572)
Total stockholders' deficit	(466)	(15,082)
Total liabilities, mezzanine equity, and stockholders' deficit	$ 2,818	$ 27,202

Unicycive Therapeutics, Inc.

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

	Three Months Ended March 31,	
	2022	**2023**
Licensing revenues:	$ -	$ 675
Operating expenses:		
Research and development	1,933	3,030
General and administrative	1,604	1,847
Total operating expenses	3,537	4,877
Loss from operations	(3,537)	(4,202)
Other income (expenses):		
Interest income	-	14
Interest expense	-	(12)
Change in fair value of warrant liability	-	(10,375)
Total other income (expenses)	-	(10,373)
Net loss	$ (3,537)	$ (14,575)
Deemed dividend to Series A-1 preferred stockholders	-	(192)
Net loss attributable to common stockholders	$ (3,537)	$ (14,767)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.24)	$ (0.97)
Weighted-average shares outstanding used in computing net loss per share, basic and diluted	15,004,617	15,232,406