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): **March 31, 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 March 31, 2023, Unicycive Therapeutics, Inc. issued a press release announcing its financial results for the full year ended December 31, 2022 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 March 31, 2023.

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: March 31, 2023

UNICYCIVE THERAPEUTICS, INC.

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

Unicycive Announces Full Year 2022 Financial Results and Provides Business Update

Closed transformational fundraise that included $30 million financing upfront with up to an additional $100 million tied to satisfaction of milestones

Financing by new and existing institutional investors from high-profile healthcare-focused funds to support launch and commercialization of investigational new drug, Renazorb™

Company on track to file New Drug Application with the U.S. Food and Drug Administration in mid-2023 with potential for approval and launch in 2024

LOS ALTOS, Calif., March 31, 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 full year ended December 31, 2022 and provided a business update.

"Our recent financing, combined with the successful, pivotal bioequivalence (BE) study for Renazorb™, is transformational for Unicycive as they support Renazorb's best-in-class potential as a treatment for hyperphosphatemia and provide funding for its commercial launch, if approved," said Shalabh Gupta, M.D., Chief Executive Officer of Unicycive. "Importantly, we are on track to file a New Drug Application (NDA) for Renazorb marketing approval with the U.S. Food and Drug Administration (FDA) in mid-year, which should provide additional funding in connection with our recent financing agreement upon approval."

"We continue to make progress with our plans for the commercialization of Renazorb for the treatment of hyperphosphatemia, where our strengthened balance sheet provides the resources needed to drive increased market awareness of Renazorb's potential best-in-class product profile and to plan and execute our go-to-market strategy to bring this novel treatment to patients. If approved, Renazorb may dramatically reduce the pill burden that patients endure with currently available medications.

"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. 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," added Dr. Gupta.

Key Highlights of the Fourth Quarter 2022 and Recent Months

- 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 to Unicycive 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 a novel feature that mandates dividends to all shareholders as the Company generates profitability.

- 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 December 2022, the Company achieved the primary endpoint in its pivotal BE study comparing Renazorb to Fosrenol®. Based on the topline results, pharmacodynamic (PD) BE of Renazorb to Fosrenol was established and met the regulatory criteria for PD BE in the healthy volunteer BE study.
- In December 2022, Unicycive reported that the Medicines and Healthcare Products Regulatory Agency (MHRA) in the United Kingdom (UK) completed review of the Clinical Trial Application (CTA) and issued a notice of acceptance for UNI-494 first-in-human Phase 1 study in healthy volunteers.

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). 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 smaller and fewer number of pills per dose and is swallowed instead of chewed.

Unicycive is looking forward to presenting data at the upcoming International Society of Nephrology's World Congress of Nephrology 2023 meeting (WCN) taking place from March 30-April 2. The data to be presented include data highlighting Renazorb's phosphate binding ability from a Phase 1 clinical study, preclinical animal data evaluating Renazorb's ability to reduce urine phosphate levels and a study that evaluated the daily medication volume of various phosphate binders to determine the option with the lowest required daily volume.

Unicycive will also present data from a study that evaluated the medication weight of various phosphate binders required to bind 1 gram of phosphorus at the National Kidney Foundation Spring Meeting (April 11-15, 2023) and highlighted Renazorb's potential best of class properties.

The totality of these data provide further evidence of the benefits of Renazorb as a powerful phosphate binder and highlight its enhanced product profile, which has the potential to improve medication compliance and, thereby, improve outcomes and quality-of-life for patients with hyperphosphatemia.

The hyperphosphatemia treatment market exceeds one billion dollars in the U.S. and is 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 for the treatment of acute kidney injury (AKI). UNI-494 is a novel proprietary 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. UNI-494 is cleaved by esterase enzymes to form nicorandil, the active metabolite.

Unicycive expects to dose the first patient in its first-in-humans Phase 1 study of UNI-494 in healthy volunteers in the United Kingdom and plans to file a corresponding Investigational New Drug (IND) application with the FDA in 2024 for a Phase 2 proof-of-concept trial in AKI patients.

The Company is looking forward to presenting a bolus of data in support of the potential for UNI-494 as a treatment for AKI at the WCN where preclinical data from a dog study that analyzed systemic exposure to UNI-494 and nicorandil will be highlighted in a poster.

Data supporting UNI-494's potential to treat acute and chronic kidney disease will be presented at the 28th International Conference on Critical Care in Nephrology: the Acute Kidney Injury & CRRT 2023 Conference (March 30-April 1).

In addition, the Company will present data at the upcoming National Kidney Foundation Spring Meeting (April 11-15, 2023), where results from three pre-clinical studies of UNI-494 underscore its potential to be reno-protective and to have low risk of drug-drug interactions, both 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.

Financial Results for the Year Ended December 31, 2022

Research and development expenses for the full year ended December 31, 2022 were $12.4 million, compared to $6.1 million for the same period in 2021. This increase was primarily attributable to development costs of $6.5 million for product formulation, clinical study, and preclinical study services in the current period.

General and administrative expenses for the year ended December 31, 2022 were $6.6 million, compared to $2.9 million for the year ended December 31, 2021. This increase was primarily attributable to an increase of $1.4 million in consulting and professional services costs. Labor costs increased $0.7 million due to hiring of new employees. Non-cash stock compensation costs increased $0.4 million. Insurance expense for directors and officers increased $0.5 million, and rent, travel, supplies and other costs increased $0.6 million.

Net loss for the 12-month period ended December 31, 2022 was $18.1 million, or $1.20 per share of common stock, compared to a net loss of $10.0 million, or $0.86 per share of common stock, for the same 12-month period in 2021. This increase was primarily attributable to increased development costs.

As of December 31, 2022, cash and cash equivalents totaled $0.5 million compared with $16.6 million in cash and cash equivalents held at December 31, 2021. 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.

Fosrenol is a registered trademark of Shire International Licensing BV.

About Unicycive Therapeutics

Unicycive Therapeutics is a biotechnology company developing novel treatments for kidney diseases. Unicycive's lead drug, Renazorb, a patent protected, 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 clinical development for the treatment of acute kidney injury. 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.

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Unicycive Therapeutics, Inc.

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

	As of December 31, 2021	As of December 31, 2022
Assets		
Current assets:		
Cash	$ 16,579	$ 455
Prepaid expenses and other current assets	1,832	2,189
Total current assets	18,411	2,644
Right of use asset, net	305	152
Property, plant and equipment, net	28	22
Total assets	$ 18,744	$ 2,818
Liabilities and stockholders' (deficit) equity		
Current liabilities:		
Accounts payable	$ 742	$ 892
Accrued liabilities	1,212	2,237
Operating lease liability - current	151	155
Total current liabilities	2,105	3,284
Operating lease liability - long term	155	-
Total liabilities	2,260	3,284
Commitments and contingencies		
Stockholders' (deficit) equity:		
Preferred stock: $0.001 par value per share—10,000,000 shares authorized at December 31, 2021 and 2022; no shares issued and outstanding at December 31, 2021 and 2022	$ -	$ -
Common stock, $0.001 par value per share – 200,000,000 shares authorized at December 31, 2021 and 2022; 14,996,534 shares issued and outstanding at December 31, 2021, and 15,231,655 shares issued and outstanding at December 31, 2022	15	15
Additional paid-in capital	32,408	33,516
Accumulated deficit	(15,939)	(33,997)
Total stockholders' equity (deficit)	16,484	(466)
Total liabilities and stockholders' equity (deficit)	$ 18,744	$ 2,818

Unicycive Therapeutics, Inc.

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

	Year Ended December 31, 2021	Year Ended December 31, 2022
Licensing revenues:	$ -	$ 951
Operating expenses:		
Research and development	6,080	12,436
General and administrative	2,897	6,567
Total operating expenses	8,977	19,003
Loss from operations	(8,977)	(18,052)
Other income (expenses):		
Interest expense	(628)	(6)
Loss on debt conversion	(431)	-
Gain on extinguishment of debt	19	-
Total other income (expenses)	(1,040)	(6)
Net loss	$ (10,017)	$ (18,058)
Net loss per share, basic and diluted	$ (0.86)	$ (1.20)
Weighted-average shares outstanding used in computing net loss per share, basic and diluted	11,675,750	15,057,049