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 28, 2024**

Unicycive Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-40582**	**81-3638692**
(State or other jurisdiction of in corporation 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 28, 2024, Unicycive Therapeutics, Inc. issued a press release announcing its financial results for the year ended December 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 March 28, 2024.
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: March 28, 2024

UNICYCIVE THERAPEUTICS, INC.

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

Exhibit 99.1

Unicycive Announces Full Year 2023 Financial Results and Provides Business Update

– Oxylanthanum Carbonate (OLC) Topline Data Expected in Q2 2024 –

– UNI-494 Granted Orphan Drug Designation in Delayed Graft Function of Acute Kidney Injury –

– UNI-494 Phase 1 Single Ascending Dose Portion of Clinical Trial Complete –

LOS ALTOS, Calif., March 28, 2024 – 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 year ended December 31, 2023, and provided a business update.

"The last several months have been extremely productive for Unicycive as we advanced both of our clinical development programs and secured new funding from several leading healthcare institutional investors," said Shalabh Gupta, M.D., Chief Executive Officer of Unicycive. "The completion of enrollment in our pivotal OLC clinical trial was a critical achievement as we believe the novel characteristics of oxylanthanum carbonate (OLC) will show its potential as a best-in-class product to treat hyperphosphatemia for patients with chronic kidney disease (CKD) on dialysis. Positive results from the trial will provide the basis to file a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA), and we remain on track with topline data expected from the trial towards the latter part of the second quarter of this year and plan to file the NDA shortly thereafter."

Dr. Gupta, added, "We also made meaningful progress with our second clinical development program, UNI-494, targeting prevention of delayed graft function (DGF) and other conditions related to acute kidney injury. Earlier this month, UNI-494 was granted orphan drug designation by the FDA for the prevention of DGF after kidney transplantation, and we presented new data showing statistically significant results for UNI-494 in a preclinical model of DGF. We successfully completed the single ascending dose (SAD) portion of our Phase 1 clinical trial, and the multiple ascending dose (MAD) portion of the study is currently ongoing. We expect to complete the Phase 1 trial and report the full results in the second half of this year."

As we close out National Kidney Awareness Month, we remain inspired to continue our research and development efforts to provide improved therapies for individuals living with kidney disease," concluded Dr. Gupta.

Key Highlights

- Completed enrollment in the open-label, single-arm, multicenter, multidose pivotal clinical trial with OLC, a next-generation lanthanum-based phosphate binding agent utilizing proprietary nanoparticle technology being developed to treat hyperphosphatemia in patients with CKD on dialysis.
- Completed a private placement with new and existing healthcare institutional investors that generated $50 million in gross proceeds to Unicycive.

- Granted orphan drug designation (ODD) by the FDA to UNI-494 for the prevention of DGF in kidney transplant patients. ODD may provide certain tax credits for qualified clinical trials, exemption of user fees, and the potential for seven years of market exclusivity after approval. UNI-494 is a cytoprotective agent that elicits an ischemic preconditioning effect by activating K_{ATP} channels in mitochondria to restore mitochondrial function.
- Presented new data demonstrating statistically significant results for UNI-494 in a preclinical model of DGF at the 29th International Conference on Advances in Critical Care Nephrology AKI and CRRT 2024. The data provides additional evidence that UNI-494 may be a valuable asset for prevention of DGF and other conditions related to acute kidney injury.
- Successfully completed the single ascending dose (SAD) portion of the Company's ongoing Phase 1 clinical trial in UNI-494. UNI-494 was well-tolerated up to 160 mg administered as a single dose and was chosen as the go-forward dose based on promising safety, tolerability, and pharmacokinetic data. In the multiple ascending dose (MAD) portion of the study, 80 mg is now being administered twice-a-day to trial participants.
- Announced that two posters related to OLC will be presented at the National Kidney Foundation Spring Clinical Meeting taking place May 14-18, 2024, in Long Beach, California.
- Announced that multiple presentations will be delivered on OLC and UNI-494 at the 61st European Renal Association (ERA) Congress taking place May 23-26, 2024, in Stockholm, Sweden.

Financial Results for the Year Ended December 31, 2023

Licensing Revenues: Licensing revenues for the year ended December 31, 2023 were $0.7 million compared to $1.0 million for the same period in 2022, due to an upfront payment for a licensing agreement entered into with Lotus International PTE Ltd in February 2023. We received an upfront payment of approximately $1.0 million associated with a licensing agreement entered into with Lee's Pharmaceutical (HK) Limited in July 2022.

Research and Development (R&D) Expenses: R&D expenses for the full year were $12.9 million, compared to $12.4 million for the same period in 2022. The increase was primarily due to a $0.7 million increase in labor costs. Non-cash stock compensation increased $0.5 million. The increases were partially offset by a decrease in drug development costs of $0.7 million.

General and Administrative (G&A) Expenses: G&A expenses were $8.5 million, compared to $6.6 million for the same period in 2022. This increase was primarily due to an increase of $1.4 million in professional services costs. Labor costs increased $0.5 million, and other administrative costs increased $0.3 million. Non-cash stock compensation costs increased $0.3 million. The increases were partially offset by a decrease in insurance expense of $0.5 million.

Other Income (Expenses): Other income (expenses) increased $9.8 million due primarily to a $10.3 million change in fair value of our warrant liability. The Company earned interest income of $0.6 million on its cash balance during the year that was partially offset by a $0.1 million increase in interest expense.

Net Loss: Net loss attributable to common stockholders for the year ended December 31, 2023 was $31.4 million, or $1.28 per share of common stock, compared to a net loss of $18.1 million, or $1.20 per share of common stock, for the same period in 2022. This increase was attributable primarily to the $10.3 million change in fair value of our warrant liability.

Cash Position: As of December 31, 2023, cash and cash equivalents totaled $9.7 million. Subsequent to year end, in March 2024, Unicycive completed a private placement of preferred stock which generated $50 million in gross proceeds. The Company believes that with the inclusion of the net proceeds from this offering, it will have sufficient resources to fund planned operations into 2026.

About Unicycive Therapeutics

Unicycive Therapeutics is a biotechnology company developing novel treatments for kidney diseases. Unicycive's lead drug candidate, oxylanthanum carbonate (OLC), is a 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 conditions related to acute kidney injury. For more information, please visit Unicycive.com and follow us on LinkedIn and YouTube.

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 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, 2023, 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:

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(650) 900-5470

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, 2022	As of December 31, 2023
Assets		
Current assets:		
Cash	$ 455	$ 9,701
Prepaid expenses and other current assets	2,189	3,698
Total current assets	2,644	13,399
Right of use asset, net	152	766
Property, plant and equipment, net	22	26
Total assets	$ 2,818	$ 14,191
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 892	$ 839
Accrued liabilities	2,237	3,234
Warrant liability	-	13,134
Operating lease liability - current	155	327
Total current liabilities	3,284	17,534
Operating lease liability - long term	-	466
Total liabilities	3,284	18,000
Commitments and contingencies		
Stockholders' deficit:		
Series A-2 preferred stock, $0.001 par value per share – zero and 43,649 shares authorized at December 31, 2022 and December 31, 2023, respectively; zero and 43,649 shares outstanding at December 31, 2022 and December 31, 2023, respectively	-	-

Preferred stock, $0.001 par value per share – 10,000,000 and 9,926,161 shares authorized at December 31, 2022 and December 31, 2023, respectively; no shares issued and outstanding at December 31, 2022 and 2023	-	-
Common stock, $0.001 par value per share – 200,000,000 shares authorized at December 31, 2022 and 2023; 15,231,655 shares issued and outstanding at December 31, 2022, and 34,756,049 shares issued and outstanding at December 31, 2023	15	35
Additional paid-in capital	33,516	60,697
Accumulated deficit	(33,997)	(64,541)
Total stockholders' deficit	(466)	(3,809)
Total liabilities and stockholders' deficit	$ 2,818	$ 14,191

Unicycive Therapeutics, Inc.

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

	Year Ended December 31, 2022	Year Ended December 31, 2023
Licensing revenues:	$ 951	$ 675
Operating expenses:		
Research and development	12,436	12,902
General and administrative	6,567	8,547
Total operating expenses	19,003	21,449
Loss from operations	(18,052)	(20,774)
Other income (expenses):		
Interest income	-	615
Interest expense	(6)	(82)
Change in fair value of warrant liability	-	(10,303)
Total other income (expenses)	(6)	(9,770)
Net loss	(18,058)	(30,544)
Deemed dividend to Series A-1 preferred stockholders	-	(867)
Net loss attributable to common stockholders	$ (18,058)	$ (31,411)
Net loss per share attributable to common stockholders, basic and diluted	$ (1.20)	$ (1.28)
Weighted-average shares outstanding used in computing net loss per share, basic and diluted	15,057,049	24,539,309