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): **November 14, 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 November 14, 2023, Unicycive Therapeutics, Inc. issued a press release announcing its financial results for the third quarter ended September 30, 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 September 30, 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: November 14, 2023

UNICYCIVE THERAPEUTICS, INC.

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

Unicycive Announces Third Quarter 2023 Financial Results and Provides Business Update

Reached Alignment with the FDA on the Data Package Requirements to File NDA for oxylanthanum carbonate (OLC)

OLC Pivotal Clinical Trial Expected to Initiate Before Year End

LOS ALTOS, Calif., November 14, 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 third quarter ended September 30, 2023, and provided a business update.

"Gaining alignment with the FDA on our clinical development plan for oxylanthanum carbonate (OLC) was a major achievement as we are one step closer to potentially bringing a much-needed therapy to individuals living with chronic kidney disease on dialysis," said Shalabh Gupta, M.D., Chief Executive Officer of Unicycive. "With clear visibility on the path forward to file an NDA, we expect to initiate the pivotal clinical trial before the end of this year. Topline data is expected in mid-2024, and we plan to finalize the NDA package and submit to the FDA shortly thereafter."

"In addition, last quarter we were excited to welcome Dr. Sara Kenkare-Mitra to our Board of Directors, adding a seasoned executive with decades of drug development and corporate leadership experience. We also remain very active within the the medical community with a booth at Kidney Week and positive results published on the phosphate binding capacity for OLC," concluded Dr. Gupta.

Key Highlights

- Alignment with the FDA:
    - Reached agreement with the U.S. Food and Drug Administration (FDA) in a Type C meeting on the overall data package requirements to file a New Drug Application (NDA) including clinical data, preclinical data, and CMC (chemistry, manufacturing, and controls). The Agency agreed with the Company's study design for a pivotal clinical trial of 60 participants to be evaluated for 4 weeks on OLC once participants are titrated to clinically effective doses. The study is designed to evaluate pharmacokinetics, tolerability and the event rate for discontinuation; therefore, there is no statistical analysis required to demonstrate efficacy. No other clinical study is required. Unicycive believes that results from this pivotal trial will enhance the OLC data package from preclinical studies and our previously disclosed bioequivalence study.

- Addition to Board of Directors:
    - Strengthened our Board of Directors with the addition of Sara Kenkare-Mitra, PhD, adding decades of drug development and corporate leadership experience. Dr. Kenkare-Mitra brings Unicycive expertise spanning research, preclinical and clinical development, translational medicine, manufacturing, and regulatory. Importantly, she has played a key role in the filing of more than 100 investigational new drug (IND) and clinical trial applications and worked on 11 drug approvals in multiple diseases.
- Publication and Awareness Campaigns:
    - Launched an unbranded educational campaign at the American Society of Nephrology's Kidney Week to address why "Less Is More" when it comes to the high pill burden currently associated with hyperphosphatemia.
    - Featured on the Nasdaq Amplify Issuer Spotlight interview series that explores how industry leaders within the small-cap community are evolving and navigating challenges in various industries.
    - The *American Journal of Nephrology* published positive results on the phosphate binding capacity for OLC showing that OLC had the lowest daily phosphate binder dose volume and the lowest volume required to bind one gram of phosphate compared to five other commercially available phosphate binders.

Financial Results for the Third Quarter Ended September 30, 2023

Licensing Revenues: Licensing revenues were $0 compared to $1.0 million for the same period in 2022, due to an upfront payment for a licensing agreement entered into with Lee's Pharmaceutical (HK) Limited in July 2022.

Research and Development (R&D) Expenses: R&D expenses were $3.4 million, compared to $4.8 million for the same period in 2022. A decrease in drug development costs of approximately $1.9 million was due to completion of significant preclinical development work in the prior period. The decrease in development costs was partially offset by increases in labor costs of $0.1 million and non-cash stock compensation costs of $0.3 million.

General and Administrative (G&A) Expenses: G&A expenses were $2.6 million, compared to $1.7 million for the same period in 2022. This increase was primarily due to an increase of $0.4 million in consulting and professional services costs. Stock compensation costs increased $0.3 million from the prior period. Labor, travel, rent, and other costs increased $0.3 million, and insurance expenses for directors and officers decreased $0.1 million.

Other Income (Expenses): Other income (expenses) increased $1.6 million due primarily to the change in fair value of our warrant liability.

Net Loss: Net loss attributable to common stockholders was $4.4 million, or $0.13 per share of common stock, compared to a net loss of $5.6 million, or $0.37 per share of common stock, for the same three-month period in 2022. This decrease was attributable primarily to a $1.4 million change in fair value of our warrant liability.

Cash Position: As of September 30, 2023, cash and cash equivalents totaled $14.3 million which is expected to last into the second half of 2024 including completion of the pivotal clinical trial and topline data for OLC.

About Oxylanthanum Carbonate (OLC)

Oxylanthanum carbonate 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). OLC 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 lower pill burden for patients in terms of number and size of pills per dose that are swallowed instead of chewed. Based on a survey conducted in 2022, Nephrologists stated that the greatest unmet need in the treatment of hyperphosphatemia with phosphate binders is a lower pill burden and better patient compliance.[1] 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.

Unicycive is seeking FDA approval of OLC via the 505(b)(2) regulatory pathway. As part of the clinical development program, two clinical studies were conducted in over 100 healthy volunteers. The first study was a dose-ranging Phase I study to determine safety and tolerability. The second study was a randomized, open-label, two-way crossover bioequivalence study to establish pharmacodynamic bioequivalence between OLC and Fosrenol. Based on the topline results of the bioequivalence study, pharmacodynamic (PD) bioequivalence of OLC to Fosrenol was established.

Fosrenol® is a registered trademark of Shire International Licensing BV.

1 Reason Research, LLC 2022 survey. Results here.

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 late preclinical development for the treatment of acute kidney injury. For more information, please visit 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 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:

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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)

	As of December 31, 2022	As of September 30, 2023 (Unaudited)
Assets		
Current assets:		
Cash	$ 455	$ 14,345
Prepaid expenses and other current assets	2,189	4,224
Total current assets	2,644	18,569
Right of use asset, net	152	845
Property, plant and equipment, net	22	28
Total assets	$ 2,818	$ 19,442
Liabilities and stockholders' (deficit) equity		
Current liabilities:		
Accounts payable	$ 892	$ 1,084
Accrued liabilities	2,237	2,530
Warrant liability	-	11,528
Operating lease liability - current	155	314
Total current liabilities	3,284	15,456
Operating lease liability - long term	-	552
Total liabilities	3,284	16,008
Commitments and contingencies		
Stockholders' (deficit) equity:		
Series A-2 preferred stock, $0.001 par value per share – zero and 43,649 shares authorized at December 31, 2022 and September 30, 2023, respectively; zero and 43,649 shares outstanding at December 31, 2022 and September 30, 2023, respectively	-	44
Preferred stock, $0.001 par value per share – 10,000,000 and 9,926,161 shares authorized at December 31, 2022 and September 30, 2023, respectively; zero shares issued and outstanding at December 31, 2022, and September 30, 2023	-	-
Common stock, $0.001 par value per share – 200,000,000 shares authorized at December 31, 2022 and September 30, 2023; 15,231,655 shares issued and outstanding at December 31, 2022, and 34,754,401 shares issued and outstanding at September 30, 2023	15	35
Additional paid-in capital	33,516	60,098
Accumulated deficit	(33,997)	(56,743)
Total stockholders' (deficit) equity	(466)	3,390
Total liabilities and stockholders' (deficit) equity	$ 2,818	$ 19,442

Unicycive Therapeutics, Inc.

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

	Three Months Ended September 30, 2022	Three Months Ended September 30, 2023
Licensing revenues:	$ 951	$ -
Operating expenses:		
Research and development	4,803	3,372
General and administrative	1,702	2,566
Total operating expenses	6,505	5,938
Loss from operations	(5,554)	(5,938)
Other income (expenses):		
Interest income	-	227
Interest expense	(3)	(18)
Change in fair value of warrant liability	-	1,396
Total other income (expenses)	(3)	1,605
Net loss	(5,557)	(4,333)
Deemed dividend to Series A-1 preferred stockholders	-	(72)
Net loss attributable to common stockholders	$ (5,557)	$ (4,405)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.37)	$ (0.13)
Weighted-average shares outstanding used in computing net loss per share, basic and diluted	15,061,995	32,633,074