

**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 11, 2021**

Unicycive Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

001-40582

(Commission File Number)

81-3638692

IRS Employer
Identification No.)

5150 El Camino Real, Suite A-32

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 11, 2021, Unicycive Therapeutics, Inc. issued a press release announcing company highlights and financial results for the third quarter ended September 30, 2021. 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 November 11, 2021.
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 12, 2021

UNICYCIVE THERAPEUTICS, INC.

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

Unicycive Therapeutics Announces Third Quarter 2021 Financial Results

Expect to receive confirmatory guidance on Renazorb regulatory pathway from the U.S. Food and Drug Administration in Q4 2021

LOS ALTOS, Calif., November 11, 2021 -- Unicycive Therapeutics, Inc. (Nasdaq: UNCY), a clinical stage biotechnology company developing therapies for patients with kidney disease, today reported financial results for the third quarter ended September 30, 2021.

Shalabh Gupta, M.D., Chief Executive Officer, stated, “With our addition to the Russell Microcap Index and conference participation, we made meaningful corporate progress to expand the interest and visibility of Unicycive within the investment community last quarter. We are also pleased to have biopharmaceutical executive Douglas Jermasek on our team whose broad experience working with kidney disease treatments has already made a huge impact.”

“In chronic kidney disease (CKD), hyperphosphatemia is caused by a chronic dysregulation of phosphates and occurs in at least 70% of patients with Stage 5 CKD. Current treatments for hyperphosphatemia come with a very high pill burden that can result in poor patient adherence. Our lead program, Renazorb, combines one of the most potent phosphate lowering agents with a smaller, easier swallowed pill to potentially improve the treatment outcomes for patients. We are working with the U.S. Food and Drug Administration (FDA) on our regulatory pathway for Renazorb and expect to receive confirmatory guidance in Q4 2021,” added Dr. Gupta.

Key Highlights and Upcoming Milestones

- Biopharmaceutical executive Douglas Jermasek appointed Executive Vice President, Corporate Strategy
- Unicycive added to the Russell Microcap Index as part of the 2021 Russell indexes reconstitution
- Presented at H.C. Wainwright 23rd Annual Global Investment Conference
- Upcoming presentation at the Benchmark Discovery One on One Investor Conference
- Expect to receive confirmatory guidance on Renazorb regulatory pathway from the FDA in Q4 2021
- Planned completion of pre-clinical studies with UNI-494 in the first half of 2022

Third Quarter 2021 Financial Results

Research and development expenses for the third quarter of 2021 were \$3.8 million, compared to \$0.3 million for the third quarter of 2020. This increase was primarily attributable to a one-time \$2.2 million increase in non-cash expense from the issuance of common stock pursuant to the anti-dilution clause in the purchase of in process research and development technology to the Renazorb licensor. This represents the final anti-dilution share issuance to the licensor.

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General and administrative expenses for the third quarter of 2021 were \$0.9 million, compared to \$0.3 million for the third quarter of 2020. This increase was primarily attributable to an increase of \$0.3 million in insurance expense for directors and officers.

Net loss for the third quarter of 2021 was \$5.2 million, or \$0.37 per share of common stock, compared to a net loss of \$0.7 million, or \$0.08 per share of common stock, for the third quarter of 2020. This increase was primarily attributable to non-cash stock issuance expense in the current period.

As of September 30, 2021, cash and cash equivalents totaled \$18 million.

About Unicycive

Unicycive 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 by the use of 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 a number of 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 pre-clinical studies 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; uncertainties of government or third party payer reimbursement; dependence on key personnel; limited experience in marketing and sales; 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. There are no guarantees that any of our technology or product candidates will be utilized or prove to be commercially successful. Additionally, there are no guarantees that future clinical trials will be completed or successful or that any therapeutics will receive regulatory approval for any indication or prove to be commercially successful. Investors should read the risk factors set forth in our Form 10-Q for the quarter ended September 30, 2021 and in our registration statement on Form S-1 and other periodic reports filed with the Securities and Exchange Commission. While the list of factors presented here is considered representative, no such list should be considered to be a complete statement of all potential risks and uncertainties. Unlisted factors may present significant additional obstacles to the realization of forward-looking statements. Forward-looking statements included herein are made as of the date hereof, and Unicycive does not undertake any obligation to update publicly such statements to reflect subsequent events or circumstances.

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

	As of December 31, 2020	As of September 30, 2021 (unaudited)
Assets		
Current assets:		
Cash	\$ -	\$ 18,011
Prepaid related party service fee	-	58
Deferred offering costs	200	-
Prepaid expenses and other current assets	4	1,713
Total current assets	<u>204</u>	<u>19,782</u>
Total assets	<u>\$ 204</u>	<u>\$ 19,782</u>
Liabilities and stockholders' (deficit) equity		
Current liabilities:		
Accounts payable	\$ 184	\$ 49
Related party service fee payable	9	-
Accrued liabilities	168	633
Convertible notes	1,528	-
Loan from stockholder	967	103
Government loan	19	-
Total current liabilities	<u>2,875</u>	<u>785</u>
Total liabilities	<u>2,875</u>	<u>785</u>
Commitments and contingencies (Note 7)		
Stockholders' (deficit) equity:		
Preferred stock: \$0.001 par value per share—10,000,000 shares authorized at December 31, 2020 and September 30, 2021 (unaudited); no shares issued and outstanding at December 31, 2020 and September 30, 2021 (unaudited)	\$ -	\$ -
Common stock, \$0.001 par value per share – 200,000,000 shares authorized at December 31, 2020 and September 30, 2021 (unaudited); 8,514,070 shares issued and outstanding at December 31, 2020, and 14,972,552 shares issued and outstanding at September 30, 2021 (unaudited)	9	15
Additional paid-in capital	3,242	32,169
Accumulated deficit	<u>(5,922)</u>	<u>(13,187)</u>
Total stockholders' (deficit) equity	<u>(2,671)</u>	<u>(18,997)</u>
Total liabilities and stockholders' (deficit) equity	<u>\$ 204</u>	<u>\$ 19,782</u>

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Unicycive Therapeutics, Inc.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2021	2020	2021
Operating expenses:				
Research and development	\$ 304	\$ 3,776	\$ 633	\$ 4,719
General and administrative	322	939	670	1,506
Total operating expenses	<u>626</u>	<u>4,715</u>	<u>1,303</u>	<u>6,225</u>
Loss from operations	(626)	(4,715)	(1,303)	(6,225)
Other expenses:				
Interest expense	(76)	(55)	(81)	(628)
Loss on debt conversion	-	(431)	-	(431)
Gain on extinguishment of debt	-	-	-	19
Total other expenses	<u>(76)</u>	<u>(486)</u>	<u>(81)</u>	<u>(1,040)</u>
Net loss	<u>\$ (702)</u>	<u>\$ (5,201)</u>	<u>\$ (1,384)</u>	<u>\$ (7,265)</u>
Net loss per share, basic and diluted	<u>\$ (0.08)</u>	<u>\$ (0.37)</u>	<u>\$ (0.16)</u>	<u>\$ (0.69)</u>
Weighted-average shares outstanding used in computing net loss per share, basic and diluted	<u>8,514,070</u>	<u>14,167,098</u>	<u>8,494,858</u>	<u>10,538,473</u>

Contacts:

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SOURCE: Unicycive Therapeutics, Inc.

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