UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 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, 2022

Acurx Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware	001-40536	82-3733567
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

259 Liberty Avenue, Staten Island, NY 10305
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (917)533-1469

Not applicable
(Former name or former address, if changed since last report.)

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 communications 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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, par value $0.001 per share	**ACXP**	**The Nasdaq Stock Market LLC**

Indicate by check mark whether the registrant is an emerging growth company 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 Condition.

On November 14, 2022, Acurx Pharmaceuticals, Inc. (the "Company") issued a press release announcing its financial results for the third quarter ended September 30, 2022 and providing a business update. The full text of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information in this Current Report on Form 8-K (including Exhibit 99.1) shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Press Release, dated November 14, 2022.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

Signatures

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed by the undersigned hereunto duly authorized.

Acurx Pharmaceuticals, Inc.

Date: November 14, 2022

By: /s/ David P. Luci
Name: David P. Luci
Title: President and Chief Executive Officer

Exhibit 99.1

For Immediate Release – 7:01 am ET on Monday, November 14, 2022

Acurx Pharmaceuticals, Inc. Reports Third Quarter 2022 Results and Provides Business Update

Staten Island, NY, November 14, 2022 — Acurx Pharmaceuticals, Inc. (NASDAQ: ACXP) ("Acurx" or the "Company"), a clinical stage biopharmaceutical company developing a new class of antibiotics for difficult-to-treat bacterial infections, announced today certain financial and operational results for the quarter ended September 30, 2022.

Highlights of, and certain events subsequent to, the third quarter of 2022 include:

- Enrollment continues in the Company's ongoing Phase 2b clinical trial of patients with*C. difficile* Infection (CDI);
- Due to slower than expected enrollment, the Company has added several clinical trial sites and anticipates that a total of up to 30 clinical trial sites will participate in the Phase 2b clinical trial;
- The Company has continued its R&D collaboration with Leiden University Medical Center (Holland) to further evaluate the mechanism-of-action of Acurx's inhibitors against the DNA pol IIIC enzyme, which is the bacterial target of our antibiotic product pipeline for the systemic treatment (IV and oral) of other gram-positive bacterial infections.
- The Company has now completed certain portions of its laboratory study at the University of Houston comparing the killing effect of ibezapolstat to vancomycin, fidaxomicin and metronidazole using both in vitro and ex vivo analyses. Certain results were presented at the Anaerobe Society of America annual scientific conference and results demonstrated that ibezapolstat has favorable killing kinetics compared to vancomycin to treat *C. difficile* infection at standard and high bacterial concentrations, supporting continued development of this first-in-class antibiotic to treat *C. difficile* Infection.

  Scientific presentations of various aspects of ibezapolstat data were presented on behalf of the Company at two recent, prominent scientific conferences as follows:

  • The Antimicrobial Resistance Conference (September 7, 2022);
  • ID Week (October 20, 2022)
- In July 2022, the Company raised $4.225 million of gross proceeds by consummating a registered direct offering to one U.S. institutional investor and three executives of the Company at $3.25 per share (for the U.S. institutional investor) and $3.80 per share (for the Company's executives who invested $225,000 in total) with a total of 1,159,211 common shares and 130,769 pre-funded warrants issued. Warrants to purchase common stock totaled 2,579,960 with warrant coverage at an exercise price of $3.25 per share for the U.S. institutional investor and $3.55 per share for the Company's executives.

Third Quarter 2022 Financial Results

The Company ended the third quarter on September 30, 2022, with cash totaling $10.6 million compared to $13.0 million as of December 31, 2021.

Research and development expenses for the three months ended September 30, 2022 were $1.6 million compared to $1.1 million for the three months ended September 30, 2021. The increase was due to an increase in Phase 2b trial related costs and an increase in consulting costs primarily related thereto. For the nine months ended September 30, 2022, research and development expenses were $3.3 million versus $1.3 million for the nine months ended September 30, 2021. This increase was due primarily to Phase 2b trial related costs in the current nine-month period and an increase in consulting costs related thereto.

General and administrative expenses for the three months ended September 30, 2022 were $2.0 million compared to $3.5 million for the three months ended September 30, 2021. The decrease was primarily due to a decrease in share-based compensation related to the Company's initial public offering and a decrease in legal fees associated with the Company's intellectual property estate. For the nine months ended September 30, 2022, general and administrative expenses were $5.5 million versus $8.9 million for the nine months ended September 30, 2021. The decrease was primarily attributable to a decrease in professional fees and stock-based compensation related to the Company's initial public offering, partially offset by an increase in insurance costs.

The Company reported a net loss of $3.5 million or $0.32 per diluted share for the three months ended September 30, 2022 compared to a net loss of $4.6 million or $0.46 per diluted share for the three months ended September 30, 2021, and a net loss of $8.8 million or $0.84 per share for the nine months ended September 30, 2022, compared to a net loss of $10.1 million or $1.27 per diluted share for the nine months ended September 30, 2021 for the reasons previously mentioned.

The Company had 11,592,609 shares outstanding as of September 30, 2022.

Conference Call

As previously announced, David P. Luci, President and Chief Executive Officer, and Robert G. Shawah, Chief Financial Officer, will host a conference call to discuss the results and provide a business update as follows:

Date: Monday, November 14, 2022

Time: 8:30 a.m. ET

Toll free (U.S.): 877-790-1503

International: Click here for participant international Toll-Free access numbers
https://www.incommconferencing.com/international-dial-in

Conference ID: 13733824

About Ibezapolstat

Ibezapolstat is a novel, orally administered antibiotic being developed as a Gram-Positive Selective Spectrum (GPSS™) antibacterial. It is the first of a new class of DNA polymerase IIIC inhibitors under development by Acurx to treat bacterial infections. Ibezapolstat's unique spectrum of activity, which includes *C. difficile* but spares other Firmicutes and the important Actinobacteria phyla, appears to contribute to the maintenance of a healthy gut microbiome.

The Company successfully completed Phase 1 and Phase 2a clinical trials of ibezapolstat. The Phase 2a trial demonstrated 100% clinical cure and 100% sustained clinical cure in patients with *C. difficile* Infection (CDI), along with beneficial microbiome changes during treatment including overgrowth of Actinobacteria and Firmicutes phylum species while on therapy and new findings which demonstrate potentially beneficial effects on bile acid metabolism. Acurx is currently enrolling patients in its Phase 2b 64-patient, randomized (1-to-1), non-inferiority, double-blind trial of oral ibezapolstat compared to oral vancomycin, a standard of care to treat CDI.

In June 2018, ibezapolstat was designated by the U.S. Food and Drug Administration (FDA) as a Qualified Infectious Disease Product (QIDP) for the treatment of patients with CDI and will be eligible to benefit from the incentives for the development of new antibiotics established under the Generating New Antibiotic Incentives Now (GAIN) Act. In January 2019, FDA granted “Fast Track” designation to ibezapolstat for the treatment of patients with CDI. The CDC has designated *C. difficile* as an urgent threat highlighting the need for new antibiotics to treat CDI.

About Acurx Pharmaceuticals, Inc.

Acurx Pharmaceuticals is a clinical stage biopharmaceutical company focused on developing new antibiotics for difficult to treat infections. The Company's approach is to develop antibiotic candidates that target the DNA polymerase IIIC enzyme and its R&D pipeline includes antibiotic product candidates that target Gram-positive bacteria, including Clostridioides difficile, methicillin-resistant Staphylococcus aureus (MRSA), vancomycin resistant Enterococcus (VRE) and drug-resistant Streptococcus pneumoniae (DRSP).

To learn more about Acurx Pharmaceuticals and its product pipeline, please visit www.acurxpharma.com.

Forward-Looking Statements

Any statements in this press release about our future expectations, plans and prospects, including statements regarding our strategy, future operations, prospects, plans and objectives, and other statements containing the words "believes," "anticipates," "plans," "expects," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: whether ibezapolstat will benefit from the QIDP designation; whether ibezapolstat will advance through the clinical trial process on a timely basis; whether the results of the clinical trials of ibezapolstat will warrant the submission of applications for marketing approval, and if so, whether ibezapolstat will receive approval from the FDA or equivalent foreign regulatory agencies where approval is sought; whether, if ibezapolstat obtains approval, it will be successfully distributed and marketed; and other risks and uncertainties described in the Company’s annual report filed with the Securities and Exchange Commission on Form 10-K for the year ended December 31, 2021, and in the Company’s subsequent filings with the Securities and Exchange Commission. Such forward-looking statements speak only as of the date of this press release, and Acurx disclaims any intent or obligation to update these forward-looking statements to reflect events or circumstances after the date of such statements, except as may be required by law.

Investor Contact:

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ACURX PHARMACEUTICALS, INC.
CONDENSED INTERIM BALANCE SHEETS

	September 30, 2022 (unaudited)	December 31, 2021 (Note 2)
ASSETS		
CURRENT ASSETS		
Cash	$ 10,607,341	$ 12,958,846
Prepaid Expenses	337,807	295,304
TOTAL ASSETS	$ 10,945,148	$ 13,254,150
LIABILITIES AND SHAREHOLDERS’ EQUITY		
CURRENT LIABILITIES		
Accounts Payable and Accrued Expenses	$ 1,182,080	$ 843,909
TOTAL CURRENT LIABILITIES	1,182,080	843,909
TOTAL LIABILITIES	1,182,080	843,909
COMMITMENTS AND CONTINGENCIES		
SHAREHOLDERS' EQUITY		
Common Stock; $.001 par value, 200,000,000 shares authorized, 11,592,609 and 10,215,792 shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively	11,593	10,216

Additional Paid-In Capital	45,132,049	38,948,334
Accumulated Deficit	(35,380,574)	(26,548,309)
TOTAL SHAREHOLDERS' EQUITY	9,763,068	12,410,241
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 10,945,148	$ 13,254,150

ACURX PHARMACEUTICALS, INC.
CONDENSED INTERIM STATEMENTS OF OPERATIONS

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	**2021**	**2022**	**2021**
	(unaudited)	**(unaudited)**	**(unaudited)**	**(unaudited)**
OPERATING EXPENSES				
Research and Development	$ 1,591,043	$ 1,126,972	$ 3,321,623	$ 1,313,954
General and Administrative	1,950,551	3,515,250	5,510,642	8,873,160
TOTAL OPERATING EXPENSES	3,541,594	4,642,222	8,832,265	10,187,114
Gain on Forgiveness of Paycheck Protection Program Loan	—	—	—	66,503
NET LOSS	$ (3,541,594)	$ (4,642,222)	$ (8,832,265)	$ (10,120,611)
LOSS PER SHARE				
Basic and diluted net loss per common share/units	$ (0.32)	$ (0.46)	$ (0.84)	$ (1.27)
Weighted average common shares/units outstanding basic and diluted	11,148,402	10,116,403	10,551,503	7,988,563