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 13, 2024

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 13, 2024, Acurx Pharmaceuticals, Inc. (the "Company") issued a press release announcing its financial results for the third quarter ended September 30, 2024 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 13, 2024.
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 13, 2024

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 Wednesday, November 13, 2024

Acurx Pharmaceuticals, Inc. Reports Third Quarter 2024 Results and Provides Business Update

Staten Island, NY, November 13, 2024 — Acurx Pharmaceuticals, Inc. (NASDAQ: ACXP) ("we" or "Acurx" or the "Company"), a late-stage biopharmaceutical company developing a new class of antibiotics for difficult-to-treat bacterial infections, announced today certain financial and operational results for the third quarter ended September 30, 2024.

Highlights of the third quarter ended September 30, 2024, or in some cases shortly thereafter, include:

- In July 2024, results from the ibezapolstat (IBZ) Phase 2 clinical trial in patients with C.*difficile* Infection (CDI) were presented at the 17th Biennial Congress of the Anaerobe Society of the Americas by Taryn A. Eubank, PharmD, BCIDP, Research Assistant Professor, University of Houston College of Pharmacy delivered an oral presentation entitled: "Clinical Efficacy of Ibezapolstat in CDI: Results from Phase 2 trials."

- Also in July 2024, and very timely given our late-stage development progress, the USPTO (United States Patent and Trademark Office) granted Acurx a new patent for ibezapolstat which specifically encompasses the "treatment of *C. difficile* Infection while reducing recurrence of infection and improving the health of the gut microbiome. This patent expires in June 2042 and we believe will provide an important downstream competitive advantage.

- In August 2024, we submitted our request to FDA for a meeting to review our manufacturing processes and specifications for drug substance and final product and packaging (a "CMC Meeting) in order to commence Phase 3 clinical trials. This FDA submission is customary and follows our successful End of Ph2 clinical meeting with FDA which confirmed our Ph3 clinical trial readiness. We anticipate convening a meeting with FDA regarding CMC in the fourth quarter.

- In September 2024, a presentation was given by Executive Chairman, Bob DeLuccia, at the World Antimicrobial Resistance Scientific Congress held in Philadelphia. In his presentation at the Innovation Showcase session, he highlighted that we have a complete roadmap, not only for the required components of our phase 3 clinical program, but also what's required for ultimate filing of an NDA (or New Drug Application) which is to be followed by submissions for Marketing Authorizations in other countries around the world. He also presented an update on the Company's preclinical GPSS® (Gram Positive Selective Spectrum) program for systemic oral and IV treatment of other gram-positive infections including, MRSA, VRE and DRSP.

- Also in September 2024, we participated at the 8th Annual *C. Difficile* Symposium (or ICDS) in Bled, Slovenia, which is the premier global scientific venue for the review of *C. Difficile* research. At the ICDS Meeting, two presentations were made on behalf of the Company.

- Additionally in September 2024, we announced that selected ACX-375 DNA pol IIIC analogues demonstrated in vitro activity against *B. anthracis* (or Anthrax), which is a Bioterrorism Category A pathogen, including activity against ciprofloxacin-resistant Anthrax. This work was performed at two independent qualified laboratories including the University of Florida. Planning is underway for an Anthrax bioterrorism development program.

- In October 2024, we participated at IDWeek in Los Angeles, the annual scientific conference of the Infectious Diseases Society of America. Drs. Kevin Garey and Taryn Eubank presented a scientific poster showing that in the Phase 2b clinical trial, ibezapolstat had comparable clinical cure and sustained clinical cure rates and safety profile to vancomycin. Also, 5 of 5 ibezapolstat patients who were followed for 3 months after end of treatment (EOT) experienced no recurrence. Ibezapolstat-treated patients showed decreased concentrations of fecal primary bile acids, and higher ratios of secondary to primary bile acids than vancomycin-treated patients.

- International regulatory filing initiatives will continue in Q4 2024.

Third Quarter 2024 Financial Results

- **Cash Position**:
  The Company ended the quarter with cash totaling $5.8 million, compared to $7.5 million as of December 31, 2023. During the third quarter, the Company raised additional proceeds under its ATM financing program, with gross proceeds of approximately $1.6 million.

- **R&D Expenses**:
  Research and development expenses for the three months ended September 30, 2024 were $1.2 million compared to $1.3 million for the three months ended September 30, 2023. The decrease was due primarily to an increase in manufacturing related costs during the quarter of $0.1 million, offset by a reduction in consulting fees of $0.2 million. For the nine months ended September 30, 2024 research & development expenses were $4.6 million compared to $4.1 million for the nine months ended September 30, 2023, an increase of $0.5 million primarily due to $0.9 million increase in manufacturing related costs, offset by $0.4 million decrease in consulting fees.

- **G&A Expenses**:
  General and administrative expenses for the three months ended September 30, 2024 were $1.6 million compared to $1.8 million for the three months ended September 30, 2023, a decrease of $0.2 million. The decrease was primarily due to $0.2 million increase in professional fees, a $0.1 million increase in compensation costs, offset by a $0.5 million decrease in non cash share-based compensation related costs. For the nine months ended September 30, 2024, general and administrative expenses were $6.7 million compared to $5.4 million for the nine months ended September 30, 2023, an increase of $1.3 million. The increase was primarily due to $1.1 million increase in professional fees and a $0.2 million increase in legal costs.

- **Net Income/Loss**:
  The Company reported a net loss of $2.8 million or $0.17 per diluted share for the three months ended September 30, 2024 compared to a net loss of $3.1 million or $0.24 per diluted share for the three months ended September 30, 2023, and a net loss of $11.3 million or $0.71 per share for the nine months ended September 30, 2024, compared to a net loss of $9.5 million or $0.77 per share for the nine months ended September 30, 2023 for the reasons previously mentioned.

  The Company had 16,770,378 shares outstanding as of September 30, 2024.

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:	Wednesday, November 13, 2024
Time:	8:00 a.m. ET
Toll free (U.S. and International):	877-790-1503
Conference ID:	13749688

About Ibezapolstat

Ibezapolstat is the Company's lead antibiotic candidate preparing to advance to international Phase 3 clinical trials to treat patients with*C. difficile* Infection (CDI). 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.

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 late-stage biopharmaceutical company focused on developing a new class of small molecule antibiotics for difficult-to-treat bacterial infections. The Company's approach is to develop antibiotic candidates with a Gram-positive selective spectrum (GPSS®) that blocks the active site of the Gram+ specific bacterial enzyme DNA polymerase IIIC (pol IIIC), inhibiting DNA replication and leading to Gram-positive bacterial cell death. 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 visitwww.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, 2023, 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:

Acurx Pharmaceuticals, Inc.
David P. Luci, President & Chief Executive Officer
Tel: 917-533-1469
Email: davidluci@acurxpharma.com

Source: Acurx Pharmaceuticals, Inc.

ACURX PHARMACEUTICALS, INC.

CONDENSED INTERIM BALANCE SHEETS

	September 30, 2024 (unaudited)	December 31, 2023 (Note 2)
ASSETS		
CURRENT ASSETS		
Cash	$ 5,762,564	$ 7,474,188
Other Receivable	97,373	129,159
Prepaid Expenses	122,822	105,776
TOTAL ASSETS	$ 5,982,759	$ 7,709,123

LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts Payable and Accrued Expenses	$ 3,318,765	$ 3,042,438
TOTAL CURRENT LIABILITIES	3,318,765	3,042,438
TOTAL LIABILITIES	3,318,765	3,042,438
COMMITMENTS AND CONTINGENCIES		
SHAREHOLDERS' EQUITY		
Common Stock; $.001 par value, 200,000,000 shares authorized, 16,770,378 and 14,468,229 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively	16,770	14,468
Additional Paid-In Capital	67,187,389	57,871,070
Accumulated Deficit	(64,540,165)	(53,218,853)
TOTAL SHAREHOLDERS' EQUITY	2,663,994	4,666,685
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 5,982,759	$ 7,709,123

ACURX PHARMACEUTICALS, INC.

CONDENSED INTERIM STATEMENTS OF OPERATIONS

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	**2023**	**2024**	**2023**
	(unaudited)	**(unaudited)**	**(unaudited)**	**(unaudited)**
OPERATING EXPENSES				
Research and Development	$ 1,198,184	$ 1,348,985	$ 4,578,777	$ 4,100,954
General and Administrative	1,623,413	1,765,996	6,742,535	5,362,224
TOTAL OPERATING EXPENSES	2,821,597	3,114,981	11,321,312	9,463,178
NET LOSS	$ (2,821,597)	$ (3,114,981)	$ (11,321,312)	$ (9,463,178)
LOSS PER SHARE				
Basic and diluted net loss per common share	$ (0.17)	$ (0.24)	$ (0.71)	$ (0.77)
Weighted average common shares outstanding, basic and diluted	16,363,473	13,005,128	15,907,778	12,282,004