

**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): May 13, 2025

Acurx Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-40536
(Commission
File Number)

82-3733567
(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 May 13, 2025, Acurx Pharmaceuticals, Inc. (the "Company") issued a press release announcing its financial results for the first quarter ended March 31, 2025 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 May 13, 2025.
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.

Date: May 13, 2025

Acurx Pharmaceuticals, Inc.

By: /s/ David P. Luci

Name: David P. Luci

Title: President and Chief Executive Officer

For Immediate Release — 7:01 am ET on Tuesday, May 13, 2025

**Acurx Pharmaceuticals, Inc. Reports First Quarter Results
and Provides Business Update**

Staten Island, NY, May 13, 2025—Acurx Pharmaceuticals, Inc. (NASDAQ: ACXP) (“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 first quarter ended March 31, 2025.

Highlights of the first quarter ended March 31, 2025, or in some cases shortly thereafter, include:

- In January 2025, the Company announced it had closed a \$2.5 million registered direct offering priced at the market under Nasdaq rules.
- Also in January 2025, we announced that we received positive regulatory guidance from the European Medicines Agency (EMA) for the ibezapolstat (IBZ) Phase 3 clinical trial program, which is aligned with FDA on matters of manufacturing, non-clinical and clinical aspects of the Phase 3 program. The EMA guidance also confirmed ibezapolstat's regulatory pathway for a Marketing Authorization Application to be filed by the Company after successful completion of the Phase 3 clinical trials. With mutually consistent feedback from both EMA and FDA, Acurx is well positioned to commence our international Phase 3 registration program.
- In February 2025 and in March 2025, we announced new publications in the Journal of Antimicrobial Agents and Chemotherapeutics of two very important non-clinical studies which we believe we can leverage to show further positive differentiation for competitive advantage of IBZ vs all other antibiotics used for the first line therapy of *C. difficile* infection. And, given our clinical results to date, we're hopeful that this anti-recurrence effect of IBZ could mitigate the need for expensive microbiome therapeutic agents to prevent recurrent CDI.
- In February 2025, we announced positive results from this first study, conducted by Dr. Justin McPherson from the University of Houston and funded by the National Institute of Allergy and Infectious Diseases (or NIAID). It was an in-silico study that predicted the microbiome-restorative potential of IBZ for treating CDI. Our scientific advisors consider this to be a major finding which provides a mechanistic explanation for IBZ's selectivity in that the predicted bactericidal interaction between IBZ and its target, the DNA pol IIIC enzyme, allows regrowth of gut microbes known to confer health benefits.
- In March 2025, we announced the second study, conducted by Dr. Trenton Wolfe, from the University of Montana, which was funded by the National Institute of Allergy and Infectious Diseases (NIAID), the National Cancer Institute (NCI), National Center for Advancing Translational Sciences (NCATS), and the Company. This study is the first ever head-to-head comparison of gut microbiome changes associated with IBZ when compared to other anti-CDI antibiotics in a germ-free mouse model. The data showed that changes in alpha and beta microbiome diversities following IBZ treatment were less pronounced compared to those observed in vancomycin (VAN)-or metronidazole (MET)-treated groups, complementing prior Phase 2 clinical findings showing IBZ's more selective antibacterial activity. Further, and very importantly, notable differences were observed between the microbiome of IBZ-and the fidaxomicin (FDX)-treated groups, which may allow for differentiation of these two anti-CDI antibiotics in future studies. These results establish IBZ's differentiating effects on the gut microbiome, indicating a more selective spectrum of microbiome alteration compared to broader-spectrum antibiotics like VAN and MET and a narrower spectrum of microbiome alteration compared to FDX.

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- Also in February 2025, the Japanese Patent Office granted a new patent for our DNA polymerase IIIC inhibitors which expires in December 2039, subject to extension. This constitutes a significant building block for our ongoing development of ACX-375C, our pre-clinical antibiotic candidate targeting the treatment of MRSA, VRE and Anthrax infections.
 - In March 2025, we announced the closing of a registered direct offering and concurrent private placement, raising gross proceeds of \$1.1 million.
 - In April 2025, the Indian Patent Office granted a new patent for our DNA polymerase IIIC inhibitors which expires in December 2039, subject to extension. This constitutes another significant building block for our ongoing development of ACX-375.
 - In May 2025, we closed an equity line of credit with Lincoln Park Capital for up to \$12 million of additional funding.

First Quarter 2025 Financial Results

Cash Position:

The Company ended the quarter with cash totaling \$4.6 million, compared to \$3.7 million as of December 31, 2024. The Company raised a total of approximately \$3.6 million of gross proceeds thru two Registered Direct Offerings.

R&D Expenses:

Research and development expenses for the three months ended March 31, 2025 were \$0.6 million compared to \$1.6 million for the three months ended March 31, 2024, a decrease of \$1.0 million. The decrease was due primarily to a decrease in manufacturing costs of \$0.4 million, and a decrease in consulting costs of \$0.6 million as a result of the prior year trial related expenses.

G&A Expenses:

General and administrative expenses for the three months ended March 31, 2025 were \$1.6 million compared to \$2.8 million for the three months ended March 31, 2024, a decrease of \$1.2 million. The decrease was primarily due to \$0.7 million decrease in professional fees resulting from lower consulting expenses, and a \$0.6 million decrease in share-based compensation costs.

Net Income/Loss:

The Company reported a net loss of \$2.1 million or \$0.11 per diluted share for the three months ended March 31, 2025 compared to a net loss of \$4.4 million or \$0.28 per diluted share for the three months ended March 31, 2024, for the reasons previously mentioned.

The Company had 22,397,511 shares outstanding as of March 31, 2025.

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: Tuesday, May 13, 2025
Time: 8:00 a.m. ET
Toll free (U.S.): 1-877-790-1503; Conference ID: 13753625
International: Click here for participant international Toll-Free access numbers
<https://www.incommconferencing.com/international-dial-in>

About Ibezapolstat

Ibezapolstat is the Company's lead antibiotic candidate advancing 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 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, 2024, 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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Source: Acurx Pharmaceuticals, Inc.

ACURX PHARMACEUTICALS, INC.

CONDENSED INTERIM BALANCE SHEETS

	March 31, 2025	December 31, 2024
ASSETS		
CURRENT ASSETS		
Cash	\$ 4,643,887	\$ 3,706,713
Other Receivable	—	51,127
Prepaid Expenses	161,574	100,123
TOTAL ASSETS	\$ 4,805,461	\$ 3,857,963
LIABILITIES AND SHAREHOLDERS' EQUITY		

CURRENT LIABILITIES		
Accounts Payable and Accrued Expenses	\$ 2,494,062	\$ 3,242,842
TOTAL CURRENT LIABILITIES	<u>2,494,062</u>	<u>3,242,842</u>
TOTAL LIABILITIES	<u>2,494,062</u>	<u>3,242,842</u>
COMMITMENTS AND CONTINGENCIES		
SHAREHOLDERS' EQUITY		
Common Stock; \$.001 par value, 200,000,000 shares authorized, 22,397,511 and 17,030,686 shares issued and outstanding at March 31, 2025 and December 31, 2024, respectively	22,398	17,031
Additional Paid-In Capital	71,760,150	67,920,046
Accumulated Deficit	<u>(69,471,149)</u>	<u>(67,321,956)</u>
TOTAL SHAREHOLDERS' EQUITY	<u>2,311,399</u>	<u>615,121</u>
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	<u>\$ 4,805,461</u>	<u>\$ 3,857,963</u>

ACURX PHARMACEUTICALS, INC.
CONDENSED INTERIM STATEMENTS OF OPERATIONS

	Three Months Ended March 31,	
	2025	2024
	(unaudited)	(unaudited)
OPERATING EXPENSES		
Research and Development	\$ 598,798	\$ 1,555,011
General and Administrative	<u>1,550,395</u>	<u>2,822,878</u>
TOTAL OPERATING EXPENSES	<u>2,149,193</u>	<u>4,377,889</u>
NET LOSS	<u>\$ (2,149,193)</u>	<u>\$ (4,377,889)</u>
LOSS PER SHARE		
Basic and diluted net loss per common share	<u>\$ (0.11)</u>	<u>\$ (0.28)</u>
Weighted average common shares outstanding, basic and diluted	<u>20,038,648</u>	<u>15,472,507</u>