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): August 14, 2023

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 x

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 August 14, 2023, Acurx Pharmaceuticals, Inc. issued a press release announcing its financial results for the second quarter ended June 30, 2023 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 August 14, 2023.
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: August 14, 2023

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, August 14, 2023

Acurx Pharmaceuticals, Inc. Reports Second Quarter 2023 Results and Provides Business Update

Staten Island, NY, August 14, 2023 — 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 second quarter ended June 30, 2023.

Highlights of the second quarter ended June 30, 2023 include:

- Acurx continues to enroll patients in its Phase 2b clinical trial, which includes 28 U.S. clinical trial sites, for patients with C. *difficile* infection (CDI);
- The Phase 2b clinical trial will compare the efficacy of oral ibezapolstat, the Company's lead antibiotic candidate, to oral vancomycin, the current standard of care for patients with CDI;
- Acurx anticipates completing enrollment of the 36 patients required for an interim review of the Phase 2b data by a newly appointed Independent Data Monitoring Committee (IDMC) in the coming months, with only 5 patients to enroll forward;
- In April 2023 two presentations were made at the 33rd Annual European Congress of Clinical Microbiology and Infectious Disease (ECCMID) in Copenhagen. First, a scientific poster entitled "Novel Pharmacology and Susceptibility of Ibezapolstat Against *C. difficile* Isolates with Reduced Susceptibility to *C. difficile*-directed Antibiotics" was presented by Dr. Kevin Garey, Professor and Chair, University of Houston College of Pharmacy, and Principal Investigator for microbiome aspects of our ibezapolstat clinical trial program. Second, Acurx Executive Chairman, Bob DeLuccia, presented an update regarding the Company's preclinical, systemic oral and IV program for treatment of other gram-positive infections caused by MRSA, VRE and DRSP at the "Pipeline Corner" featured session at ECCMID, organized by Dr. Ursula Theuretzbacher, a world-renowned microbiology expert involved in antibacterial drug research, discovery and development strategies and policies for clinical and public health needs. These presentations are available on the Company's website at www.acurxpharma.com .
- Acurx announced that it has been approved for presentations in 2H 2023 at two of the most prestigious scientific conferences in our sector; namely, the World Antimicrobial Resistance Conference (Philadelphia, PA) in September 2023 as well as at ID Week sponsored by the Infectious Disease Society of America (Boston, MA) in October 2023.
- The Company is continuing its R&D collaboration with Leiden University Medical Center (Holland) under a previously awarded grant from the Dutch Government of approximately $500,000 USD 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 pipeline for the systemic treatment (IV and oral) of gram-positive bacterial infections;
- The Company was notified by CARB-X that its application for a non-dilutive grant to fund its pre-clinical antibiotic candidate, ACX375C, was not approved. CARB-X noted that the 2023 round of funding was very competitive and that their Scientific Advisory Board was enthusiastic about pol IIIC as the bacterial target of our molecules and that the sufficiently good PK and safety properties of the compounds justified the proposed lead optimization plan. CARB-X encouraged us to re-apply for potential future requests for proposals or RFPs that CARB-X will continue to promulgate from time to time for CARB-X funding consideration.

Second Quarter 2023 Financial Results

- **Cash Position**:
  The Company ended the second quarter with cash totaling $9.1 million compared to $9.1 million as of December 31, 2022.
- **R&D Expenses**:
  Research and development expenses for the three months ended June 30, 2023 were $1.7 million compared to $0.9 million for the three months ended June 30, 2022. The increase was due to an increase in Phase 2b trial related costs. For the six months ended June 30, 2023 research and development expenses were $2.8 million compared to $1.7 million for the six months ended June 30, 2022. The increase is due primarily to an increase in Phase 2b trial related costs and an increase in consulting costs.
- **G&A Expenses**:
  General and administrative expenses for the three months ended June 30, 2023 were $1.7 million compared to $1.7 million for the three months ended June 30, 2022. Professional fees decreased by $0.1 million, offset by an increase of $0.1 million in employee related compensation costs. For the six months ended June 30, 2023, general and administrative expenses were $3.6 million compared to $3.6 million for the six months ended June 30, 2022. Professional fees decreased by $0.2 million, offset by an increase of $0.2 million in employee related compensation costs.
- **Net Income/Loss**:
  The Company reported a net loss of $3.4 million or $0.28 per diluted share for the three months ended June 30, 2023, compared to a net loss of $2.6 million or $0.26 per diluted share for the three months ended June 30, 2022, and a net loss of $6.3 million or $0.53 per diluted share for the six months ended June 30, 2023, compared to a net loss of $5.3 million or $0.52 per diluted share for the six months ended June 30, 2022 for the reasons previously mentioned.

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, August 14, 2023
Time:	8:00 a.m. ET
Toll free (U.S. and International):	877-790-1503
Conference ID:	13740293

About the Ibezapolstat Phase 2 Clinical Trial

The completed multicenter, open-label single-arm segment (Phase 2a) study is now followed by a double-blind, randomized, active-controlled, non-inferiority, segment (Phase 2b) at 28 US clinical trial sites which together comprise the Phase 2 clinical trial (see https://clinicaltrials.gov/ct2/show/NCT04247542). This Phase 2 clinical trial is designed to evaluate the clinical efficacy of ibezapolstat in the treatment of CDI including pharmacokinetics and microbiome changes from baseline and continue to test for anti-recurrence microbiome properties seen in the Phase 2a trial, including the treatment-related changes in alpha diversity and bacterial abundance and effects on bile acid metabolism.

The completed Phase 2a segment of this trial was an open label cohort of up to 20 subjects from study centers in the United States. In this cohort, 10 patients with diarrhea caused by *C. difficile* were treated with ibezapolstat 450 mg orally, twice daily for 10 days. All patients were followed for recurrence for 28± 2 days. Per protocol, after 10 patients of the projected 20 Phase 2a patients completed treatment (100% cured infection at End of Treatment), the Trial Oversight Committee assessed the safety and tolerability and made its recommendation regarding early termination of the Phase 2a study and advancement to the Ph2b segment. In the currently enrolling Phase 2b, trial segment, patients with CDI will be enrolled and randomized in a 1:1 ratio to either ibezapolstat 450 mg every 12 hours or vancomycin 125 mg orally every 6 hours, in each case, for 10 days and followed for 28 ± 2 days following the end of treatment for recurrence of CDI. The two treatments will be identical in appearance, dosing times, and number of capsules administered to maintain the blind. This Phase 2 clinical trial will also evaluate pharmacokinetics (PK) and microbiome changes and continue to test for anti-recurrence microbiome properties, including the change from baseline in alpha diversity and bacterial abundance, especially overgrowth of healthy gut microbiota Actinobacteria and Firmicute phylum species during and after therapy. In the event non-inferiority of ibezapolstat to vancomycin is demonstrated, further analysis will be conducted to test for superiority.

Phase 2a data demonstrated complete eradication of colonic *C. difficile* by day three of treatment with ibezapolstat as well as the observed overgrowth of healthy gut microbiota, Actinobacteria and Firmicute phyla species, during and after therapy. Very importantly, emerging data show an increased concentration of secondary bile acids during and following ibezapolstat therapy which is known to correlate with colonization resistance against *C. difficile*. A decrease in primary bile acids and the favorable increase in the ratio of secondary-to-primary bile acids suggest that ibezapolstat may reduce the likelihood of CDI recurrence when compared to vancomycin

About the Microbiome in *Clostridioides difficile* Infection (CDI) and Bile Acid Metabolism

C. difficile can be a normal component of the healthy gut microbiome, but when the microbiome is thrown out of balance, the *C. difficile* can thrive and cause an infection. After colonization with *C. difficile*, the organism produces and releases the main virulence factors, the two large clostridial toxins A (TcdA) and B (TcdB). (Kachrimanidou, Microorganisms 2020, 8, 200; doi:10.3390/microorganisms8020200.) TcdA and TcdB are exotoxins that bind to human intestinal epithelial cells and are responsible for inflammation, fluid and mucous secretion, as well as damage to the intestinal mucosa.

Bile acids perform many functional roles in the GI tract, with one of the most important being maintenance of a healthy microbiome by inhibiting *C. difficile* growth. Primary bile acids, which are secreted by the liver into the intestines, promote germination of *C. difficile* spores and thereby increase the risk of recurrent CDI after successful treatment of an initial episode. On the other hand, secondary bile acids, which are produced by normal gut microbiota through metabolism of primary bile acids, do not induce *C. difficile* sporulation and therefore protect against recurrent disease. Since ibezapolstat treatment leads to minimal disruption of the gut microbiome, bacterial production of secondary bile acids continues which may contribute to an anti-recurrence effect.

About *Clostridioides difficile* Infection (CDI)

According to the 2017 Update (published February 2018) of the *Clinical Practice Guidelines for C. difficile Infection by the Infectious Diseases Society of America (IDSA) and Society or Healthcare Epidemiology of America (SHEA),* CDI remains a significant medical problem in hospitals, in long-term care facilities and in the community. *C. difficile* is one of the most common causes of health care- associated infections in U.S. hospitals (Lessa, et al, 2015, New England Journal of Medicine). Recent estimates suggest *C. difficile* approaches 500,000 infections annually in the U.S. and is associated with approximately 20,000 deaths annually. (Guh, 2020, New England Journal of Medicine). Based on internal estimates, the recurrence rate of two of the three antibiotics currently used to treat CDI is between 20% and 40% among approximately 150,000 patients treated. We believe the annual incidence of CDI in the U.S. approaches 600,000 infections and a mortality rate of approximately 9.3%.

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 early-stage 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.

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 United States Food and Drug Administration or equivalent foreign regulatory agencies where approval is sought; whether, if ibezapolstat obtains approval, it will be successfully distributed and marketed; and other factors. In addition, the forward-looking statements included in this press release represent our views as of August 14, 2023. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we specifically disclaim any obligation to do so.

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, 2022, 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

	June 30, 2023 (unaudited)	December 31, 2022 (Note 2)
ASSETS		
CURRENT ASSETS		
Cash	$ 9,145,835	$ 9,111,751
Prepaid Expenses	89,942	264,955
TOTAL ASSETS	$ 9,235,777	$ 9,376,706
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts Payable and Accrued Expenses	$ 3,019,408	$ 2,061,685
TOTAL CURRENT LIABILITIES	3,019,408	2,061,685
TOTAL LIABILITIES	3,019,408	2,061,685
COMMITMENTS AND CONTINGENCIES		
SHAREHOLDERS' EQUITY		
Common Stock; $.001 par value, 200,000,000 shares authorized, 13,005,128 and 11,627,609 shares issued and outstanding at June 30, 2023 and December 31, 2022, respectively	13,005	11,628
Additional Paid-In Capital	51,192,646	45,944,478
Accumulated Deficit	(44,989,282)	(38,641,085)
TOTAL SHAREHOLDERS' EQUITY	6,216,369	7,315,021
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 9,235,777	$ 9,376,706

ACURX PHARMACEUTICALS, INC.

CONDENSED INTERIM STATEMENTS OF OPERATIONS

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
	(unaudited)	(unaudited)	(unaudited)	(unaudited)
OPERATING EXPENSES				
Research and Development	$ 1,736,386	$ 911,692	$ 2,751,969	$ 1,730,580
General and Administrative	1,708,854	1,708,841	3,596,228	3,560,090
TOTAL OPERATING EXPENSES	3,445,240	2,620,533	6,348,197	5,290,670
NET LOSS	$ (3,445,240)	$ (2,620,533)	$ (6,348,197)	$ (5,290,670)
LOSS PER SHARE				
Basic and diluted net loss per common share	$ (0.28)	$ (0.26)	$ (0.53)	$ (0.52)
Weighted average common shares outstanding basic and diluted	12,186,481	10,263,202	11,914,449	10,248,107