November 14, 2023

Acurx Pharmaceuticals

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

STATEN ISLAND, N.Y., Nov. 14, 2023 /PRNewswire/ -- 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 third quarter ended September 30, 2023.

Highlights of the third quarter ended September 30, 2023, and in some cases shortly thereafter, include:

On October 2, 2023, Acurx ended enrollment in its Phase 2b clinical trial of ibezapolstat, its lead antibiotic candidate, for the treatment of patients with C. difficile infection, or CDI;

On November 2, 2023, Acurx reported top-line data from the Phase 2 clinical trial including the ibezapolstat clinical cure rate at end of treatment, or EOT, of 96% (25/26) including 100% in Phase 2a (10/10) and 94% in Phase 2b (15/16) as well as the cure rate for oral vancomycin at EOT of 100% (14/14);

Ibezapolstat will now move forward to Phase 3 clinical trials. Preparation underway for End-of-Phase 2 FDA Meeting and advancement to Phase 3

No safety concerns were reported in either arm of the Phase 2b clinical trial or in the Phase 2a open label trial;

In consultation with its scientific advisors, the Company determined that clear evidence of clinical cure was established with ibezapolstat and ibezapolstat is clinically comparable to vancomycin, the standard of care to treat CDI;

Further data will be provided when available on all of the secondary and exploratory endpoints in the Phase 2b trial, including sustained clinical cure data, extended clinical cure data up to 94 days and impact on the microbiome when compared to vancomycin.

The Company anticipates that these secondary and exploratory endpoints will provide clear separation between these two therapeutic options and provide validation for front-line use of ibezapolstat to treat patients with CDI;.

In September 2023, the World Antimicrobial Resistance (AMR) Congress convened its annual meeting in Philadelphia where experts in the field from both the public and private sectors weighed in on the latest innovations to address AMR. Our Executive Chairman, Bob DeLuccia, presented an update entitled: "Novel DNA pol IIIC Inhibitors for Gram-positive Bacterial Infections: Preparing for the Next Pandemic".

The IDSA (Infectious Diseases Society of America) convened its annual meeting, called ID Week, in Boston from October 11-15, 2023. Acurx was featured at two scheduled events:

First, an oral presentation by Dr. Kevin Garey, Professor and Chair, University of Houston College of Pharmacy, and the Principal Investigator for microbiome aspects of our ibezapolstat clinical trial program, was given on October 14 entitled: Elucidating the Gram-Positive Selective Spectrum Activity of Ibezapolstat; Secondary Analysis from the phase 2a trial.

Second, Acurx presented at the symposium entitled, "New Antimicrobials in the Pipeline" on October 12. At the symposium, Acurx presentation was entitled: "Novel DNA pol IIIC Inhibitors for Gram-positive Bacterial Infections."

Three scientific posters were presented during the CLOSTPATH conference held in Banff, Canada from September 19 to 23, 2023 and provided new information further supporting ibezapolstat's unique pharmacologic profile:

The first entitled: "Ibezapolstat modulates Clostridioides difficile virulence factors in vitro" showed Ibezapolstat reduces toxin production by the C. difficile bacteria…

The second entitled: "C. difficile In Vitro Biofilm Studies of Ibezapolstat And Comparator Antibiotics" showed ibezapolstat was as effective as the currently-used anti-C. difficile antibiotics fidaxomicin, vancomycin and metronidazole in reducing reduce biofilm-embedded C. difficile…

The third entitled: "Metagenomic Evaluation of Ibezapolstat Compared to Other Anti-*C. difficile* Agents" showed ibezapolstat and fidaxomicin both caused favorable proportional increases in Bacteroidetes but distinct from vancomycin and metronidazole, which caused unfavorable proportional increases in Proteobacteria.

All the presentations described above are available on our website.

Third Quarter 2023 Financial Results

Cash Position:
The Company ended the third quarter with cash totaling $7.1 million, compared to $9.1 million as of December 31, 2022. After the quarter end, the Company received an additional $2.2 million in cash associated with the conversion of approximately 680,000 warrants, which resulted in the issuance of approximately 680,000 shares.

R&D Expenses:
Research and development expenses for the three months ended September 30, 2023, were $1.3 million compared to $1.6 million for the three months ended September 30, 2022. The decrease was due to the timing of Phase 2b trial related costs. For the nine months ended September 30, 2023, research and development expenses were $4.1 million versus $3.3 million for the nine months ended September 30, 2022. The increase is due primarily to Phase 2b trial related costs and an increase in consulting costs.

G&A Expenses:
General and administrative expenses for the three months ended September 30, 2023, were $1.8 million compared to $2.0 million for the three months ended September 30, 2022. The

decrease was due primarily to a $0.2 million decrease in professional fees. For the nine months ended September 30, 2023, general and administrative expenses were $5.4 million versus $5.5 million for the nine months ended September 30, 2022. The amounts reflect a decrease in professional fees of $0.3 million, offset by an increase of $0.2 million in share-based compensation.

Net Loss:
The Company reported a net loss of $3.1 million or $0.24 per diluted share for the three months ended September 30, 2023 compared to a net loss of $3.5 million or $0.32 per diluted share for the three months ended September 30, 2022, and a net loss of $9.5 million or $0.77 per share for the nine months ended September 30, 2023, compared to a net loss of $8.8 million or $0.84 per diluted share for the nine months ended September 30, 2022 for the reasons previously mentioned.

The Company had 13,005,128 shares outstanding as of September 30, 2023.

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, November 14, 2023
Time:	8:00 a.m. ET
Toll free (U.S. and International):	877-790-1503
Conference ID:	13742354

About the Ibezapolstat Phase 2 Clinical Trial

On November 2, 2023, we reported top-line data from the Phase 2 clinical trial including the ibezapolstat clinical cure rate at end of treatment, or EOT, of 96% (25/26) including 100% in Phase 2a (10/10) and 94% in Phase 2b (15/16) as well as the cure rate for oral vancomycin at EOT of 100% (14/14). No safety concerns were reported in either arm of the Phase 2b clinical trial or in the Phase 2a open label trial. In consultation with its scientific advisors, the Company has determined that clear evidence of clinical cure has been established with ibezapolstat and is clinically comparable to vancomycin. Ibezapolstat will now move forward to Phase 3 clinical trials. Further data will be provided when available on all of the secondary and exploratory endpoints in the Phase 2b trial, including sustained clinical cure data, extended clinical cure data up to 94 days and impact on the microbiome compared to vancomycin.We anticipate that these secondary and exploratory endpoints will provide clear separation between these two therapeutic options.

The completed multicenter, open-label single-arm segment (Phase 2a) study was 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 was 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 now completed Phase 2b trial segment, 32 patients with CDI were 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 were 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 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.

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.

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.

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ACURX PHARMACEUTICALS, INC.

CONDENSED INTERIM BALANCE SHEETS

	September 30, 2023 (unaudited)	December 31, 2022 (Note 2)
ASSETS		
CURRENT ASSETS		
Cash	$ 7,052,329	$ 9,111,751
Prepaid Expenses	105,722	264,955
TOTAL ASSETS	$ 7,158,051	$ 9,376,706
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts Payable and Accrued Expenses	$ 3,223,378	$ 2,061,685
TOTAL CURRENT LIABILITIES	3,223,378	2,061,685
TOTAL LIABILITIES	3,223,378	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 September 30, 2023 and December 31, 2022, respectively	13,005	11,628
Additional Paid-In Capital	52,025,931	45,944,478
Accumulated Deficit	(48,104,263)	(38,641,085)
TOTAL SHAREHOLDERS' EQUITY	3,934,673	7,315,021
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 7,158,051	$ 9,376,706

ACURX PHARMACEUTICALS, INC.

CONDENSED INTERIM STATEMENTS OF OPERATIONS

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
	(unaudited)	(unaudited)	(unaudited)	(unaudited)
OPERATING EXPENSES				
Research and Development	$ 1,348,985	$ 1,591,043	$ 4,100,954	$ 3,321,623
General and Administrative	1,765,996	1,950,551	5,362,224	5,510,642
TOTAL OPERATING EXPENSES	3,114,981	3,541,594	9,463,178	8,832,265
NET LOSS	$ (3,114,981)	$ (3,541,594)	$ (9,463,178)	$ (8,832,265)
LOSS PER SHARE				
Basic and diluted net loss per common share	$ (0.24)	$ (0.32)	$ (0.77)	$ (0.84)
Weighted average common shares outstanding basic and diluted	13,005,128	11,148,402	12,282,004	10,551,503

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