August 9, 2024

Acurx Pharmaceuticals

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

STATEN ISLAND, N.Y., Aug. 9, 2024 /PRNewswire/ -- 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 second quarter ended June 30, 2024.

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

- In April 2024, we completed a successful End-of-Phase 2 Clinical Meeting with FDA and confirmed Phase 3 Readiness for ibezapolstat (IBZ) to enter Phase 3 clinical trials for the treatment of C. difficile infection. Agreement with FDA was reached on key elements to move forward with our international Phase 3 clinical trial program. Agreement was also reached with FDA on the complete non-clinical and clinical development plan for filing of a New Drug Application (NDA) for marketing approval. We've since continued activities to advance IBZ into international Phase 3 clinical trials for treatment of C. difficile Infection. In parallel, we're also preparing to submit requests for regulatory guidance to initiate clinical trials in the European Union, the United Kingdom, Japan and Canada.

- Also in April 2024, we attended the European Society of Microbiology and Infectious Disease (or ESCMID) scientific congress. Dr. Kevin Garey provided an oral presentation of our Phase 2 data entitled: "A Phase 2, Randomized, Double-Blind Study of Ibezapolstat Compared with Vancomycin for the Treatment of C. difficile Infection." Dr. Garey is Professor and Chair, University of Houston College of Pharmacy, and the Principal Investigator for microbiology and microbiome aspects of the IBZ clinical trial program and Acurx Scientific Advisory Board member. The oral presentation included additional analyses of clinical and microbiological data and is available on our website at www.acurxpharma.com. The complete Phase 2 results are being prepared for submission to a prominent scientific journal for publication. The oral presentation is available on our website at www.acurxpharma.com.

- In May 2024, we announced that the European Medicines Agency (or EMA) approved our application to be designated as a small to medium sized enterprise (or SME) in Europe which provides for certain benefits including fee reductions and other support from the EMA for seeking a Marketing Authorization for Europe.

- In July 2024, results from the IBZ Phase 2 clinical trial in patients with C. difficile Infection 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 IBZ 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 think 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.

- Throughout the rest of this year, we'll continue to roll out our Phase 2 results in either oral presentations or scientific posters (in some cases both), which will include results from new analyses as data become available, at various prominent scientific conferences including:
    - In September 2024, the World Antimicrobial Resistance conference in Philadelphia;
    - In September 2024, the 8th International C. difficile Symposium (or ICDS meeting) in Bled, Slovania, which is the premiere global venue for the review of C. difficile research; and
    - In October 2024, we will be presenting at the annual meeting of the Infectious Diseases Society of America (or ID Week) in Los Angeles.

- International Regulatory Initiatives will continue in 2H 2024.

Second Quarter of 2024 Financial Results

- **Cash Position**:
  The Company ended the quarter with cash totaling $6.4 million, compared to $7.5 million as of December 31, 2023. During the second quarter, the Company sold an additional 133,066 shares under its ATM financing program, with gross proceeds of approximately $0.3 million.

- **R&D Expenses**:
  Research and development expenses for the three months ended June 30, 2024 were

$1.8 million compared to $1.7 million for the three months ended June 30, 2023. The increase was due primarily to an increase in manufacturing related costs during the quarter of $0.4 million, partially offset by a reduction in consulting fees of $0.3 million. For the six months ended June 30, 2024 research & development expenses were $3.4 million compared to $2.8 million for the six months ended June 30, 2023, an increase of $0.6 million primarily due to $0.8 million increase in manufacturing related costs offset by $0.2 million decrease in consulting fees.

- **G&A Expenses**:
  General and administrative expenses for the three months ended June 30, 2024 were $2.3 million compared to $1.7 million for the three months ended June 30, 2023, an increase of $0.6 million. The increase was primarily due to $0.3 million increase in professional fees and $0.2 million increase in non cash share-based compensation related costs. For the six months ended June 30, 2024, general and administrative expenses were $5.1 million compared to $3.6 million for the six months ended June 30, 2023, an increase of $1.5 million. The increase was primarily due to $1.0 million increase in professional fees, $0.4 million increase in non cash share-based compensation costs and $0.1 million increase in legal costs

- **Net Income/Loss**:
  The Company reported a net loss of $4.1 million or $0.26 per diluted share for the three months ended June 30, 2024 compared to a net loss of $3.4 million or $0.28 per diluted share for the three months ended June 30, 2023, and a net loss of $8.5 million or $0.54 per share for the six months ended June 30, 2024, compared to a net loss of $6.3 million or $0.53 per share for the reasons previously mentioned.

The Company had 15,996,168 shares outstanding as of June 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:	Friday, August 9, 2024
Time:	8:00 a.m. ET
Toll free (U.S. and International):	877-790-1503
Conference ID:	13747936

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 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, 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.

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ITEM 1. CONDENSED INTERIM FINANCIAL STATEMENTS.

ACURX PHARMACEUTICALS, INC.
CONDENSED INTERIM BALANCE SHEETS

	June 30, 2024 (unaudited)	December 31, 2023 (Note 2)
ASSETS		
CURRENT ASSETS		
Cash	$ 6,360,858	$ 7,474,188
Other Receivable	51,127	129,159
Prepaid Expenses	168,407	105,776
TOTAL ASSETS	$ 6,580,392	$ 7,709,123
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts Payable and Accrued Expenses	$ 3,152,917	$ 3,042,438
TOTAL CURRENT LIABILITIES	3,152,917	3,042,438
TOTAL LIABILITIES	3,152,917	3,042,438
COMMITMENTS AND CONTINGENCIES		
SHAREHOLDERS' EQUITY		
Common Stock; $.001 par value, 200,000,000 shares authorized, 15,996,168 and 14,468,229 shares issued and outstanding at June 30, 2024 and December 31, 2023, respectively	15,996	14,468
Additional Paid-In Capital	65,130,047	57,871,070
Accumulated Deficit	(61,718,568)	(53,218,853)
TOTAL SHAREHOLDERS' EQUITY	3,427,475	4,666,685
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 6,580,392	$ 7,709,123

ACURX PHARMACEUTICALS, INC.
CONDENSED INTERIM STATEMENTS OF OPERATIONS

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024 (unaudited)	2023 (unaudited)	2024 (unaudited)	2023 (unaudited)
OPERATING EXPENSES				
Research and Development	$ 1,825,582	$ 1,736,386	$ 3,380,593	$ 2,751,969
General and Administrative	2,296,244	1,708,854	5,119,122	3,596,228
TOTAL OPERATING EXPENSES	4,121,826	3,445,240	8,499,715	6,348,197
NET LOSS	$ (4,121,826)	$ (3,445,240)	$ (8,499,715)	$ (6,348,197)
LOSS PER SHARE				
Basic and diluted net loss per common share	$ (0.26)	$ (0.28)	$ (0.54)	$ (0.53)
Weighted average common shares outstanding, basic and diluted	15,824,654	12,186,481	15,677,426	11,914,449

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