May 15, 2024

Acurx Pharmaceuticals

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

STATEN ISLAND, N.Y., May 15, 2024 /PRNewswire/ -- Acurx Pharmaceuticals, Inc. (NASDAQ: ACXP) ("we" or "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 first quarter ended March 31, 2024.

Highlights of the first quarter ended March 31, 2024, or in some cases shortly thereafter, include:

- On January 17, 2024, we announced positive comparative microbiology and microbiome data for ibezapolstat in CDI patients from the Phase 2b clinical trial segment. Ibezapolstat outperformed vancomycin showing eradication of fecal *C. difficile* at Day 3 of treatment in 15 of 16 treated patients (94%), versus vancomycin which had eradication of *C. difficile* in 10 of 14 treated patients (71%).

- Additional data from this Phase 2b clinical trial showed ibezapolstat, but not vancomycin, consistently preserved and allowed regrowth of key gut bacterial species believed to confer health benefits including to prevent recurrence of CDI.

- Additional data from exploratory endpoints will provide further favorable separation between these two therapeutic options in our Phase 3 clinical trial program and ultimately in the marketplace, if approved.

- An End of Phase 2 Meeting was recently conducted with FDA in April 2024. At the FDA meeting, we reached agreement on key elements of our Phase 3 program and readiness to proceed to Phase 3. We also reached agreement on the regulatory pathway for a new drug application (or NDA) filing for marketing approval in the U.S.

- 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.

- We attended the European Society of Microbiology and Infectious Disease (or ESCMID) scientific congress held in April 2024 where Dr. Kevin Garey, Professor and Chair, University of Houston College of Pharmacy, and the Principal Investigator for microbiology and microbiome aspects of the ibezapolstat clinical trial program and Acurx Scientific Advisory Board member gave 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 Clostridioides difficile Infection." The presentation

included additional analyses of clinical and microbiological data and is available on our website at www.acurxpharma.com.

- Throughout the rest of this year, we will continue to roll out our Phase 2 results in either oral presentations or scientific posters (in some cases both), which by the way, will include results from new analyses as data become available, at various prominent scientific conferences including:
  - The Houston Cdiff and Microbiome conference;
  - The Anaerobe Society of America annual conference;
  - The World Antimicrobial Resistance conference;
  - The International Cdifficile Symposium; and
  - The annual meeting of the Infectious Diseases Society of America (or IDWeek).

First Quarter of 2024 Financial Results

- **Cash Position**:
  The Company ended the quarter with cash totaling $8.9 million, compared to $7.5 million as of December 31, 2023. In the first quarter, the Company sold 1,121,793 shares under its ATM financing program, with gross proceeds of approximately $4.4 million.

- **R&D Expenses**:
  Research and development expenses for the three months ended March 31, 2024 were $1.6 million compared to $1.0 million for the three months ended March 31, 2023. The increase was due primarily to an increase in manufacturing related costs.

- **G&A Expenses**:
  General and administrative expenses for the three months ended March 31, 2024 were $2.8 million compared to $1.9 million for the three months ended March 31, 2023. The increase was due primarily to a $0.7 million increase in professional fees and a $0.2 million increase in non-cash share-based compensation.

- **Net Income/Loss**:
  The Company reported a net loss of $4.4 million or $0.28 per diluted share for the three months ended March 31, 2024 compared to a net loss of $2.9 million or $0.25 per diluted share for the three months ended March 31, 2023 for the reasons previously mentioned.

  The Company had 15,757,102 shares outstanding as of March 31, 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, May 15, 2024
Time:	8:00 a.m. ET
Toll free (U.S. and International):	877-790-1503
Conference ID:	13746308

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, 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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ACURX PHARMACEUTICALS, INC.

CONDENSED INTERIM BALANCE SHEETS

	March 31, 2024 (unaudited)	December 31, 2023 (Note 2)
ASSETS		
CURRENT ASSETS		
Cash	$ 8,920,926	$ 7,474,188
Other Receivable	—	129,159
Prepaid Expenses	187,908	105,776
TOTAL ASSETS	$ 9,108,834	$ 7,709,123
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts Payable and Accrued Expenses	$ 3,110,242	$ 3,042,438
TOTAL CURRENT LIABILITIES	3,110,242	3,042,438
TOTAL LIABILITIES	3,110,242	3,042,438
COMMITMENTS AND CONTINGENCIES		
SHAREHOLDERS' EQUITY		
Common Stock; $.001 par value, 200,000,000 shares authorized, 15,757,102 and 14,468,229 shares issued and outstanding at March 31, 2024 and December 31, 2023, respectively	15,757	14,468
Additional Paid-In Capital	63,579,577	57,871,070
Accumulated Deficit	(57,596,742)	(53,218,853)
TOTAL SHAREHOLDERS' EQUITY	5,998,592	4,666,685
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 9,108,834	$ 7,709,123

ACURX PHARMACEUTICALS, INC.

CONDENSED INTERIM STATEMENTS OF OPERATIONS

	Three Months Ended March 31,	
	2024	**2023**
	(unaudited)	**(unaudited)**
OPERATING EXPENSES		
Research and Development	$ 1,555,011	$ 1,015,583
General and Administrative	2,822,878	1,887,374
TOTAL OPERATING EXPENSES	4,377,889	2,902,957
NET LOSS	$ (4,377,889)	$ (2,902,957)
LOSS PER SHARE		
Basic and diluted net loss per common share	$ (0.28)	$ (0.25)
Weighted average common shares outstanding, basic and diluted	15,472,507	11,639,395

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