May 11, 2022

Acurx Pharmaceuticals

Acurx Pharmaceuticals, Inc. Reports First Quarter 2022 Results and Provides Business Update

STATEN ISLAND, N.Y., May 11, 2022 /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 quarter ended March 31, 2022.

Highlights of, and certain events subsequent to, the first quarter of 2022 include:

- Enrollment continues in the Company's ongoing Phase 2b clinical trial of patients with *C. difficile* Infection (CDI) with anticipated completion of enrollment late in the second half of 2022;
- Based on the strength of our previously reported Phase 2a results (100% cure rate at end of treatment with no recurrences at Day 38 follow up visit), the Company amended the Phase 2b trial protocol to add a novel exploratory endpoint of Extended Clinical Cure, for study visits at day 56 and day 84 after the end of treatment for a selected group of subjects to evaluate the longer-term effect of ibezapolstat on the microbiome and on disease recurrence. No comparable long-term data such as this has been conducted or reported with currently used antibiotics for CDI and it is not expected to interfere with the timing of completion of the Phase 2b clinical trial;
- The Company has added several clinical trial sites and anticipates up to 24 clinical trial sites will participate in the Phase 2b clinical trial; and
- The Company has continued its R&D collaboration with Leiden University Medical Center (Holland) 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 product pipeline for the systemic treatment (IV and oral) of other gram-positive bacterial infections.

First Quarter 2022 Financial Results

Research and development expenses for the quarter ended March 31, 2022 were $0.8 million compared to $0.1 million for the quarter ended March 31, 2021. The increase was primarily due to Phase 2b trial related costs and increased consulting costs.

General and administrative expenses for the quarter ended March 31, 2022 were $1.9 million compared to $1.4 million for the quarter ended March 31, 2021. The increase was primarily due to increases in professional fees, legal and insurance costs.

The Company reported a net loss of $2.7 million or $0.26 per diluted share for the three months ended March 31, 2022 compared to a net loss of $1.5 million or $0.21 per diluted share for the three months ended March 31, 2021, for the reasons mentioned above.

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 11, 2022
Time:	8:30 a.m. ET
Toll free (U.S.):	877-790-1503
International:	Click here for participant international Toll-Free access numbers https://www.incommconferencing.com/international-dial-in
Conference ID:	13729712

About Ibezapolstat

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.

The Company successfully completed Phase 1 and Phase 2a clinical trials of ibezapolstat. The Phase 2a trial demonstrated 100% clinical cure and 100% sustained clinical cure in patients with *C. difficile* Infection (CDI), along with beneficial microbiome changes during treatment including overgrowth of Actinobacteria and Firmicutes phylum species while on therapy and new findings which demonstrate potentially beneficial effects on bile acid metabolism. Acurx is currently enrolling patients in its Phase 2b 64-patient, randomized (1-to-1), non-inferiority, double-blind trial of oral ibezapolstat compared to oral vancomycin, a standard of care to treat CDI.

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 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 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, 2021, 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:
Acurx Pharmaceuticals, Inc.
David P. Luci, President & CEO
Tel: 917-533-1469
Email: davidluci@acurxpharma.com

ACURX PHARMACEUTICALS, INC.
CONDENSED INTERIM BALANCE SHEETS

	March 31, 2022 (unaudited)	December 31, 2021
ASSETS		
CURRENT ASSETS		
Cash	$ 11,082,846	$ 12,958,846
Prepaid Expenses	239,454	295,304
TOTAL ASSETS	$ 11,322,300	$ 13,254,150
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts Payable and Accrued Expenses	$ 633,028	$ 843,909
TOTAL CURRENT LIABILITIES	633,028	843,909
TOTAL LIABILITIES	633,028	843,909
COMMITMENTS AND CONTINGENCIES		
Common Stock; $.001 par value, 200,000,000 shares authorized, 10,263,202 and 10,215,792 shares issued and outstanding at March 31, 2022 and December 31, 2021, respectively	10,263	10,216
Additional Paid-In Capital	39,897,456	38,948,334
Accumulated Deficit	(29,218,447)	(26,548,309)
TOTAL SHAREHOLDERS' EQUITY	10,689,272	12,410,241
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 11,322,300	$ 13,254,150

ACURX PHARMACEUTICALS, INC.
CONDENSED INTERIM STATEMENTS OF OPERATIONS

	Three Months Ended March 31,	
	2022 (unaudited)	2021 (unaudited)
OPERATING EXPENSES		
Research and Development	$ 818,888	$ 91,908
General and Administrative	1,851,250	1,382,421
TOTAL OPERATING EXPENSES	2,670,138	1,474,329
NET LOSS	$ (2,670,138)	$ (1,474,329)
LOSS PER SHARE		
Basic and diluted net loss per common share/units	$ (0.26)	$ (0.21)
Weighted average common shares/units outstanding basic and diluted	10,232,843	6,867,289

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