November 12, 2021

Acurx Pharmaceuticals

Acurx Pharmaceuticals, Inc. Reports Third Quarter 2021 Results and Provides Business Update

STATEN ISLAND, N.Y., Nov. 12, 2021 /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 September 30, 2021.

Highlights of, and certain events subsequent to, the third quarter of 2021 include:

- 12 clinical trial sites have been activated to commence enrollment of the Company's Phase 2b clinical trial of patients with C *difficile* infection (CDI) with enrollment expected to be completed in the second quarter of 2022;
- Additional microbiome data from the Phase 2a trial of ibezapolstat in patients with CDI were presented at two prominent scientific conferences shortly after completion of the third quarter;
- This Ph2a trial demonstrated 100% clinical cure and 100% sustained clinical cure with ibezapolstat 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
- These reported clinical results support the expectation that microbiome effects may be predictive of beneficial patient outcomes including low rates of recurrence
- The previously announced R&D program in collaboration with Leiden University Medical Center in Holland was launched 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.

Third Quarter 2021 Financial Results

Research and development expenses for the three months ended September 30, 2021 were $1.1 million compared to $0.7 million for the three months ended September 30, 2020. The increase is primarily due to Phase 2B trial related costs. For the nine-months ended September 30, 2021, research and development expenses were $1.3 million compared to $1.7 million for the nine-months ended September 30, 2020. The decrease is due to the Phase 2a trial related costs which was completed in 2020.

Selling, general and administrative expenses for the three months ended September 30, 2021 were $3.5 million compared to $0.7 million for the three months ended September 30, 2020. The increase was primarily due to non-cash stock-based compensation and increases in professional fees, insurance and legal costs.

For the nine-months ended September 30, 2021, selling, general and administrative expenses were $8.9 million compared to $1.8 million for the nine-months ended September 30, 2020. The increase in general and administrative expenses is primarily attributable to

increases in non-cash stock-based compensation, professional fees, stock-based director fees, and insurance and legal costs.

The Company reported a net loss of $4.6 million or $(0.46) per diluted share for the three months ended September 30, 2021 compared to a net loss of $1.3 million or $(0.21) per diluted share for the three months ended September 30, 2020 and a net loss of $10.1 million or $(1.27) per diluted share for the nine-months ended September 30, 2021, compared to a net loss of $3.5 million or $(0.58) per diluted share for the nine-months ended September 30, 2020, for the reasons previously mentioned.

As of September 30, 2021, the Company had a cash balance of $14.5 million.

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, November 15, 2021
Time:	8:30 a.m. ET
Toll free (U.S. and International):	877-790-1503
Conference ID:	13724324

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.

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 Company successfully completed Phase 1 and Phase 2a clinical trials of ibezapolstat and in the second half of 2021 it expects to begin enrollment of its Phase 2b vancomycin-controlled efficacy study in a 1:1 randomized trial of a total of 64 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 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 November 12, 2021. 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.

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FINANCIAL TABLES FOLLOW

ACURX PHARMACEUTICALS, INC.
CONDENSED INTERIM STATEMENTS OF OPERATIONS

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
	(unaudited)	(unaudited)	(unaudited)	(unaudited)
OPERATING EXPENSES				
Research and Development	$ 1,126,972	$ 659,977	$ 1,313,954	$ 1,745,446
General and Administrative	3,515,250	654,569	8,873,160	1,761,561
TOTAL OPERATING EXPENSES	4,642,222	1,314,546	10,187,114	3,507,007
Gain on forgiveness of Paycheck Protection Program Loan	—	—	66,503	—
NET LOSS	$ (4,642,222)	$ (1,314,546)	$ (10,120,611)	$ (3,507,007)
LOSS PER SHARE				
Basic and diluted net loss per common share/units	$ (0.46)	$ (0.21)	$ (1.27)	$ (0.58)
Weighted average pro forma shares outstanding basic and diluted	10,116,403	6,266,584	7,988,563	6,037,254

ACURX PHARMACEUTICALS, INC.
CONDENSED INTERIM BALANCE SHEETS

	September 30, 2021	December 31, 2020
	(unaudited)	
ASSETS		
CURRENT ASSETS		
Cash	$ 14,459,046	$ 3,175,411
Prepaid Expenses	530,582	48,609
TOTAL ASSETS	$ 14,989,628	$ 3,224,020
LIABILITIES AND MEMBERS' AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts Payable and Accrued Expenses	$ 712,437	$ 455,931
Paycheck Protection Program Loan	—	16,625
TOTAL CURRENT LIABILITIES	712,437	472,556
NONCURRENT LIABILITIES		
Paycheck Protection Program Loan	—	49,878
TOTAL LIABILITIES	712,437	522,434
COMMITMENTS AND CONTINGENCIES		
MEMBERS' AND SHAREHOLDERS' EQUITY		
Members' Equity, Class A	—	16,402,198
Members' Equity, Class B	—	100,000
Common Stock; $.001 par value, 200,000,000 shares authorized, 10,126,903 shares issued and outstanding at September 30, 2021	10,127	—
Additional Paid-In capital	38,188,287	—
Accumulated Deficit	(23,921,223)	(13,800,612)
TOTAL MEMBERS' AND SHAREHOLDERS' EQUITY	14,277,191	2,701,586
TOTAL LIABILITIES AND MEMBERS' AND SHAREHOLDERS' EQUITY	$ 14,989,628	$ 3,224,020

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