

Acurx Pharmaceuticals, Inc. Reports First Quarter 2026 results and Provides Business Update

STATEN ISLAND, N.Y., May 12, 2026 /PRNewswire/ -- Acurx Pharmaceuticals, Inc. (NASDAQ: ACXP) ("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 first quarter ended March 31, 2026.

Highlights of the first quarter ended March 31, 2026, or in some cases shortly thereafter, include:

- In February 2026, we announced that the USPTO granted a new patent for our DNA pol IIIC inhibitors covering composition of matter and method of use. This patent extends to December 2039, subject to extension under US patent rules. This adds to our extensive patent estate for our DNA pol IIIC inhibitors going out in some cases to 2042, subject to extension.
- In March 2026, we issued a press release announcing that we are starting up a ground-breaking ibezapolstat (IBZ) clinical trial program in patients with recurrent CDI (rCDI) that has the potential to shift the paradigm of treatment and prevention of rCDI from two agents to one. When coupled with IBZ Phase 2 results of being highly effective (96% clinical cure) in treating acute CDI with 0% recurrence in patients cured of their infection while sparing the gut microbiome, this new clinical trial strategy has the potential to position ibezapolstat to be a new standard of care as the first agent to treat both (acute) CDI and prevent rCDI.
- This new Phase 2 clinical trial in rCDI builds on ibezapolstat's strength, namely that no patients who were cured of their infection experienced a recurrence. This new trial begins with an open-label pilot study to gain experience with IBZ in up to 20 patients with multiply-recurrent CDI who had at least 3 episodes of CDI within the past 12 months. This will inform elements of a planned active-controlled, Phase 3 registration trial in the rCDI indication to be implemented following favorable results from the open-label trial. Upon subsequent successful completion of the Ph3 pivotal rCDI trial, and per the operative FDA procedure, Acurx plans to request FDA approval for treatment and prevention of rCDI under the FDA's Limited Population Pathway for Antibacterial and Antifungal Drugs Guidance for Industry.
- Acurx's clinical program in the broader acute CDI patient population is ready to advance to Phase 3 international pivotal clinical trials. In this regard, we're very excited about the FDA's recent announcement published in the New England Journal of Medicine '...that a one-trial requirement will be FDA's new default standard [i.e., for registration]'. If formalized by FDA, this would end the long-standing two-trial dogma. We look forward to FDA's further clarification and the potentially favorable implications

to our clinical development programs, such as the opportunity to seek marketing approval for the broader CDI population with one pivotal clinical trial.

- In March 2026, we announced that the Korean Patent Office granted a new patent which covers DNA pol IIIC inhibitors including compositions of matter, methods of use, and pharmaceutical compositions, which further strengthen Acurx's intellectual property portfolio and represents the most recent addition to its expanding series of granted patents in the U.S. and internationally. To date, Acurx has secured ten patents including five U.S. patents along with patents in Israel, Japan, India, Australia and Korea, all of which protect key aspects of the Company's product pipeline. Also, and very significantly, a new patent was recently issued relating to IBZ and its use to treat CDI while reducing the recurrence of the infection, as well as improving the health of the gut microbiome. Additional country level patent applications remain under review.
- In April 2026, the Company announced the closing of a registered direct offering of 825,085 shares of its common stock (or pre-funded warrants in lieu thereof) at a purchase price of \$3.03 per share (or pre-funded warrant in lieu thereof) priced at-the-market under Nasdaq rules. In addition, in a concurrent private placement, the Company issued unregistered short-term warrants to purchase up to 1,650,170 shares of common stock. The short-term warrants have an exercise price of \$2.78 per share, and are immediately exercisable upon issuance and will expire twenty-four months following the effective date of the registration statement registering the resale of the shares of common stock underlying the short-term warrants. This additional funding when coupled with the remaining availability under our Equity Line of Credit ensures that the Company has the financial resource to conduct the exploratory clinical trial in recurrent *C. difficile* infection.
- In April 2026, a scientific poster was presented at the 35th Congress of ESCMID Global (European Society of Clinical Microbiology and Infectious Diseases) held in Munich, Germany from April 17-21, 2026 showing that Acurx's orally absorbed DNA pol IIIC inhibitors in preclinical development have the unexpected benefit of gut microbiome preservation while demonstrating systemic antibacterial activity. Dr. Khurshida Begum, Research Scientist, University of Houston College of Pharmacy presented the poster demonstrating potentially therapeutic plasma levels, reduction of MRSA tissue burden and maintaining a substantially higher gut microbial diversity and community structure similar to baseline and distinct from linezolid.

First Quarter 2026 Financial Results

Cash Position:

The Company ended the quarter with cash totaling \$9.3 million, compared to \$7.6 million as of December 31, 2025. During the quarter, the Company raised a total of approximately \$3.1 million of gross proceeds through purchases under the Equity Line of Credit.

R&D Expenses:

Research and development expenses for the three months ended March 31, 2026 were \$0.3 million compared to \$0.6 million for the three months ended March 31, 2025, a decrease of \$0.3 million. The decrease was due primarily to a decrease in manufacturing costs of \$0.1

million, and a decrease in consulting costs of \$0.2 million as a result of the prior year trial preparation related expenses.

G&A Expenses:

General and administrative expenses for the three months ended March 31, 2026 were \$1.4 million compared to \$1.6 million for the three months ended March 31, 2025, a decrease of \$0.2 million. The decrease was primarily due to a \$0.1 million decrease in professional fees and a \$0.1 million decrease in legal costs.

Net Income/Loss:

The Company reported a net loss of \$1.7 million or \$0.62 per diluted share for the three months ended March 31, 2026 compared to a net loss of \$2.1 million or \$2.15 per diluted share for the three months ended March 31, 2025, all for the reasons previously mentioned.

The Company had 3,389,106 shares outstanding as of March 31, 2026.

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, May 12, 2026
Time: 8:00 a.m. ET
Toll free (U.S.): 1-877-790-1503; Access ID: 13760162
International: Click here for participant international Toll-Free access numbers
<https://www.incommconferencing.com/international-dial-in>

About Ibezapolstat

Ibezapolstat is the Company's lead antibiotic candidate preparing for advancement into international Phase 3 clinical trials to treat patients with acute C. difficile Infection (CDI) and it is also preparing for a ground-breaking clinical trial targeting the prevention of recurrent CDI (rCDI). If successful, ibezapolstat will change the treatment paradigm for CDI and rCDI by providing one therapy for the full spectrum of CDI and rCDI from first occurrence to multiply recurrent episodes.

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. As previously announced, the Company has received final EMA and FDA agreement for our ibezapolstat pivotal Phase 3 trials in CDI. Their advice included and confirmed the non-inferiority study design elements, the patient population, primary and secondary endpoints, and size of the registration safety database. Acxrx also now has a clear international roadmap for conduct of its Phase 3 program in CDI and, if successful, requirements for US NDA submission and EU Marketing Authorization.

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 III α (pol III α), 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), drug-resistant *Streptococcus pneumoniae* (DRSP) and *B. anthracis* (anthrax; a Bioterrorism Category A Threat-Level pathogen).

Acurx's lead product candidate, ibezapolstat, for the treatment of *C. difficile* Infection (CDI) is Phase 3 ready to advance to international clinical trials subject to obtaining appropriate financing. The Company recently announced the launch of a ground-breaking clinical trial with ibezapolstat in patients with multiply-recurrent CDI (rCDI) that has the potential to shift the paradigm of treatment and prevention of rCDI from two agents to one. This new clinical trial in rCDI begins with an open-label pilot trial to gain experience with IBZ in patients with multiply-recurrent CDI with at least 3 episodes of CDI within the past 12 months. This will inform elements of a planned active-controlled, Phase 3 registration trial in the rCDI indication to be implemented following favorable results from the open-label 20 patient trial. Upon subsequent successful completion of the Ph3 pivotal rCDI trial, and per the operative FDA procedure, Acurx plans to request FDA approval for treatment and prevention of rCDI under the FDA's Limited Population Pathway for Antibacterial and Antifungal Drugs (Guidance for Industry, 2020).

The Company's preclinical pipeline includes development of an oral product candidate for treatment of ABSSSI (Acute Bacterial Skin and Skin Structure Infections), upon which a development program for treatment of inhaled anthrax is being planned in parallel.

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, 2025, 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, 2026 (unaudited)	December 31, 2025 (Note 2)
<u>ASSETS</u>		
CURRENT ASSETS		
Cash	\$ 9,254,813	\$ 7,556,100
Other Receivable	56,313	48,417
Prepaid Expenses	228,826	85,018
TOTAL ASSETS	<u>\$ 9,539,952</u>	<u>\$ 7,689,535</u>
<u>LIABILITIES AND SHAREHOLDERS' EQUITY</u>		
CURRENT LIABILITIES		
Accounts Payable and Accrued Expenses	\$ 2,526,809	\$ 2,420,943
TOTAL CURRENT LIABILITIES	<u>2,526,809</u>	<u>2,420,943</u>
TOTAL LIABILITIES	<u>2,526,809</u>	<u>2,420,943</u>
COMMITMENTS AND CONTINGENCIES		
SHAREHOLDERS' EQUITY		
Preferred Stock; \$0.001 par value, 10,000,000 shares authorized, no shares issued and outstanding at March 31, 2026 and December 31, 2025	—	—
Common Stock; \$0.001 par value, 250,000,000 shares authorized, 3,389,106 and 2,348,113 shares issued and outstanding at March 31, 2026 and December 31, 2025, respectively	3,389	2,348
Additional Paid-In Capital	83,979,230	80,554,738
Accumulated Deficit	<u>(76,969,476)</u>	<u>(75,288,494)</u>
TOTAL SHAREHOLDERS' EQUITY	<u>7,013,143</u>	<u>5,268,592</u>
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	<u>\$ 9,539,952</u>	<u>\$ 7,689,535</u>

ACURX PHARMACEUTICALS, INC.
CONDENSED INTERIM STATEMENTS OF OPERATIONS

	Three Months Ended March 31,	
	2026	2025
	(unaudited)	(unaudited)
OPERATING EXPENSES		
Research and Development	\$ 341,468	\$ 598,798
General and Administrative	1,374,522	1,577,686
TOTAL OPERATING EXPENSES	1,715,990	2,176,484
OPERATING LOSS	(1,715,990)	(2,176,484)
OTHER INCOME		
Interest Income	35,008	27,291
NET LOSS	<u>\$ (1,680,982)</u>	<u>\$ (2,149,193)</u>
LOSS PER SHARE		
Basic and diluted net loss per common share	<u>\$ (0.62)</u>	<u>\$ (2.15)</u>
Weighted average common shares outstanding, basic and diluted	<u>2,718,433</u>	<u>1,001,932</u>

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