

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): August 15, 2022

Acurx Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-40536
(Commission
File Number)

82-3733567
(IRS Employer
Identification No.)

259 Liberty Avenue, Staten Island, NY 10305
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (917)533-1469

Not applicable
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

| Title of each class | Trading Symbol | Name of each exchange on which registered |
|---|-------------------|--|
| Common Stock, par value \$0.001 per share | ACXP | The Nasdaq Stock Market LLC |

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02 Results of Operations and Financial Condition.

On August 15, 2022, Acurx Pharmaceuticals, Inc. (the "Company") issued a press release announcing its financial results for the second quarter ended June 30, 2022 and providing a business update. The full text of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information in this Current Report on Form 8-K (including Exhibit 99.1) shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

| Exhibit No. | Description |
|----------------------|---|
| 99.1 | Press Release, dated August 15, 2022. |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document) |

Signatures

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed by the undersigned hereunto duly authorized.

Acurx Pharmaceuticals, Inc.

Date: August 15, 2022

By: /s/ David P. Luci

Name: David P. Luci

Title: President and Chief Executive Officer

August 15, 2022

Acurx Pharmaceuticals

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

STATEN ISLAND, N.Y., Aug. 15, 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 June 30, 2022.

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

- Enrollment continues in the Company's ongoing Phase 2b clinical trial of patients with *C. difficile* Infection (CDI);
- Due to slower than expected enrollment, the Company has added several clinical trial sites and anticipates up to 30 clinical trial sites will participate in the Phase 2b clinical trial;
- 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 IIIIC enzyme, which is the bacterial target of our antibiotic product pipeline for the systemic treatment (IV and oral) of other gram-positive bacterial infections.
- The Company has now completed certain portions of its laboratory study at the University of Houston comparing the killing effect of ibezapolstat to vancomycin, fidaxomicin and metronidazole using both in vitro and ex vivo analyses. Certain results were presented at Anaerobe 2022, the Anaerobe Society of America annual scientific conference and results demonstrated that ibezapolstat has favorable killing kinetics compared to vancomycin to treat *C. difficile* infection at standard and high bacterial concentrations, supporting continued development of a potential first-in-class antibiotic to treat *C. difficile* Infection.
 - Scientific presentations of various aspects of ibezapolstat data have been accepted at three upcoming prominent scientific conferences later this year, including:
 - The Antimicrobial Resistance Conference (September 7-8, 2022);
 - ID Week (October 19-23, 2022); and
 - C. Diff Foundation Conference (November 3-4, 2022).
- In July 2022, the Company raised \$4.225 million of gross proceeds by consummating a registered direct offering to one U.S. institutional investor and three executives of the Company at \$3.25 per share (for the U.S. institutional investor) and \$3.80 per share (for the Company's executives) with a total of 1,159,211 common shares and 130,769 pre-funded warrants issued. Warrants to purchase common stock totaled 2,579,960 with warrant coverage at an exercise price of \$3.25 per share for the U.S. institutional investor and \$3.55 per share for the Company's executives.

Second Quarter 2022 Financial Results

The Company ended the second quarter on June 30, 2022, with cash totaling \$9.1 million compared to \$13.1 million as of December 31, 2021.

Research and development expenses for the three months ended June 30, 2022 were \$0.9 million compared to \$0.1 million for the three months ended June 30, 2021. The increase is due to Phase 2b trial related costs and an increase in consulting costs primarily related thereto. For the six months ended June 30, 2022, research and development expenses were \$1.7 million versus \$0.2 million for the six months ended June 30, 2021. The increase is due primarily to Phase 2b trial related costs and an increase in consulting costs related thereto.

General and administrative expenses for the three months ended June 30, 2022 were \$1.7 million compared to \$3.9 million for the three months ended June 30, 2021. The decrease was primarily due to a decrease in professional fees and share-based compensation related to the Company's initial public offering consummated in June 2021. For the six months ended June 30, 2022, general and administrative expenses were \$3.6 million versus \$5.4 million for the six months ended June 30, 2021. The decrease is primarily attributable to a decrease in professional fees and stock-based compensation primarily related to the Company's initial public offering, partially offset by an increase in legal and insurance costs.

The Company reported a net loss of \$2.6 million or \$0.26 per diluted share for the three months ended June 30, 2022 compared to a net loss of \$4.0 million or \$ 0.57 per diluted share for the three months ended June 30, 2021, and a net loss of \$5.3 million or \$0.52 per share for the six months ended June 30, 2022, compared to a net loss of \$5.5 million or \$0.79 per diluted share for the six months ended June 30, 2021 for the reasons previously mentioned.

The Company had 10,263,202 shares outstanding as of June 30, 2022.

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, August 16, 2022
 Time: 8:30 a.m. ET
 Toll free (U.S.): 877-790-1503
 International: [Click here for participant international Toll-Free access numbers](#)
 Conference ID: 13732015

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 III C 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 III C 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

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ACURX PHARMACEUTICALS, INC. CONDENSED INTERIM BALANCE SHEETS

| | June 30, 2022 (unaudited) | December 31, 2021 (Note 2) |
|---|---------------------------------|----------------------------------|
| ASSETS | | |
| CURRENT ASSETS | | |
| Cash | \$ 9,092,197 | \$ 12,958,846 |
| Prepaid Expenses | 116,856 | 295,304 |
| TOTAL CURRENT ASSETS | 9,209,053 | 13,254,150 |
| NON CURRENT ASSETS | | |
| Deferred Offering Costs | 50,247 | — |
| TOTAL ASSETS | \$ 9,259,300 | \$ 13,254,150 |
| LIABILITIES AND SHAREHOLDERS' EQUITY | | |

| | | |
|---|---------------------|----------------------|
| CURRENT LIABILITIES | | |
| Accounts Payable and Accrued Expenses | \$ 473,879 | \$ 843,909 |
| TOTAL CURRENT LIABILITIES | 473,879 | 843,909 |
| TOTAL LIABILITIES | 473,879 | 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 June 30, 2022 and December 31, 2021, respectively | | |
| | 10,263 | 10,216 |
| Additional Paid-In Capital | 40,614,138 | 38,948,334 |
| Accumulated Deficit | (31,838,980) | (26,548,309) |
| TOTAL SHAREHOLDERS' EQUITY | 8,785,421 | 12,410,241 |
| TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY | \$ 9,259,300 | \$ 13,254,150 |

**ACURX PHARMACEUTICALS, INC.
CONDENSED INTERIM STATEMENTS OF OPERATIONS**

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|--|-----------------------------|--------------------------------------|-----------------------------|
| | 2022 (unaudited) | 2021 (unaudited) | 2022 (unaudited) | 2021 (unaudited) |
| OPERATING EXPENSES | | | | |
| Research and Development | \$ 911,692 | \$ 95,074 | \$ 1,730,580 | \$ 186,981 |
| General and Administrative | 1,708,841 | 3,975,488 | 3,560,090 | 5,357,911 |
| TOTAL OPERATING EXPENSES | 2,620,533 | 4,070,562 | 5,290,670 | 5,544,892 |
| Gain on forgiveness of Paycheck Protection Program Loan | — | 66,503 | — | 66,503 |
| NET LOSS | \$ (2,620,533) | \$ (4,004,059) | \$ (5,290,670) | \$ (5,478,389) |
| LOSS PER SHARE | | | | |
| Basic and diluted net loss per common share/units | \$ (0.26) | \$ (0.57) | \$ (0.52) | \$ (0.79) |
| Weighted average pro forma shares outstanding basic and diluted | 10,263,202 | 6,968,341 | 10,248,107 | 6,908,396 |

View original content: <https://www.pnewswire.com/news-releases/acurx-pharmaceuticals- inc-reports-second-quarter-2022-results-and-provides-business-update-301604156.html>

SOURCE Acurx Pharmaceuticals, Inc.