# 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): March 18, 2024**

# Acurx Pharmaceuticals, Inc.

**(Exact name of registrant as specified in its charter)**

| **Delaware** | **001-40536** | **82-3733567** |
|---|---|---|
| **(State or other jurisdiction of incorporation)** | **(Commission File Number)** | **(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 x

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 March 18, 2024, Acurx Pharmaceuticals, Inc. (the "Company") issued a press release announcing its financial results for the fourth quarter and full year ended December 31, 2023 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 March 18, 2024. |
| 104 | Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101) |

**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: March 18, 2024

By: /s/ David P. Luci
Name: David P. Luci
Title: President and Chief Executive Officer

**Exhibit 99.1**

March 18, 2024

Acurx Pharmaceuticals

# Acurx Pharmaceuticals, Inc. Reports Fourth Quarter and Full Year 2023 Results and Provides Business Update

STATEN ISLAND, N.Y., March 18, 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 fourth quarter and full year ended December 31, 2023.

Highlights of the fourth quarter ended December 31, 2023, or in some cases shortly thereafter, include:

- In October 2023, we ended enrollment in our Phase 2b clinical trial of ibezapolstat, our lead antibiotic candidate, for the treatment of patients with *C. difficile* infection, or CDI. In November 2023, we reported top-line data from the Phase 2b clinical trial, including overall results from the full Phase 2 study, demonstrating an ibezapolstat clinical cure rate at end of 10-days' oral treatment, or EOT, of 96% (25 of 26 patients) which included 100% cure in Phase 2a (10 of 10 patients) and 94% in Phase 2b (15 of 16 patients) compared with the vancomycin control arm of 100% (14 of 14 patients) at EOT. No safety concerns were reported in either arm of the Phase 2b clinical trial and ibezapolstat was well tolerated in all patients in both the Phase 2a open label trial and in the Phase 2b vancomycin-controlled segment. In consultation with its scientific advisors, the Company determined that based on review of aggregate blinded data the Phase 2b vancomycin-controlled trial segment was terminated early due to success showing high observed clinical cure rates with no emerging safety concerns. We also stated at that further data would be provided as they become available on secondary and exploratory endpoints from the Phase 2b trial segment, including sustained clinical cure data at 30 days after EOT, and Extended Clinical cure data up to 94 days as well as comparative data on the impact to the patient's microbiome.
- In December 2023, we announced the sustained clinical cure data. These data showed that in the Phase 2b clinical trial segment 100% or 15 out of 15 patients who were cured at EOT remained cured with no reinfection 30 days later while vancomycin experienced a reinfection rate of 14.3% (2 of 14 patients).
- In January 2024, the Company 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.
- The Company anticipates that additional data from the secondary and 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. Additional analyses regarding other secondary and exploratory endpoints will be forthcoming as data become available.

- Having robust preclinical, clinical and manufacturing data-to-date, the Company submitted a formidable Information Package to FDA in February 2024 along with a Request for an End of Phase 2 Meeting which was granted by the FDA and is scheduled to occur in April. We anticipate discussing our Phase 3 clinical trial mandate at this meeting and would anticipate documented meeting minutes from FDA in the second quarter of 2024.
- The European Medicines Agency (or EMA) approved our application to be designated as a small to medium sized enterprise (or SME) in Europe in February 2024 which provides for certain benefits including fee reductions and other support from the EMA for seeking a Marketing Authorization for Europe.
- In October 2023, Dr. Kevin Garey presented on behalf of the Company at ID Week with selective spectrum of activity data from our Phase 2a clinical trial. Dr. Garey is Professor and Chair, University of Houston College of Pharmacy, and the Principal Investigator for microbiome aspects of our ibezapolstat clinical trial program. Also at ID Week, Bob DeLuccia, our Executive Chairman, presented our new class of novel DNA pol IIIC inhibitors in our pre-clinical pipeline at the symposium entitled, "New Antimicrobials in the Pipeline."
- In November 2023, the Company filed an amendment to its shelf registration statement with the SEC and launched a $17 million at-the-market equity offering program (or ATM), with Alliance Global Partners acting as sales agent to the Company. Proceeds from the ATM have been and, in the future, are expect to be used for general corporate purposes going forward including our planned Phase 3 clinical trial mandate.

**Fourth Quarter and Full Year 2023 Financial Results**

- **Cash Position**:
  The Company ended the year with cash totaling $7.5 million, compared to $9.1 million as of December 31, 2022. Subsequent to year-end, the Company sold an additional 1,121,793 shares under its ATM financing program, with gross proceeds of approximately $4.5 million.

- **R&D Expenses**:
  Research and development expenses for the three months ended December 31, 2023 were $1.9 million compared to $1.4 million for the three months ended December 31, 2022. The increase was due to the timing of Phase 2b trial related costs and an increase in consulting costs. For the year ended December 31, 2023, research and development expenses were $6.0 million versus $4.8 million for the year ended December 31, 2022. The increase is due primarily to Phase 2b trial-related costs and an increase in consulting costs.

- **G&A Expenses**:
  General and administrative expenses for the three months ended December 31, 2023 were $3.2 million compared to $1.8 million for the three months ended December 31, 2022. The increase was due primarily to a $0.8 million increase in professional fees, a $0.1 million increase in share-based compensation, and a $0.3 million increase in employee compensation costs. For the year ended December 31, 2023, general and administrative expenses were $8.5 million versus $7.3 million for the year ended December 31, 2022. The amounts reflect an increase in professional fees of $0.5 million, an increase of $0.3 million in share-based compensation, and an increase of $0.3 million in employee compensation costs.

- **Net Income/Loss**:
  The Company reported a net loss of $5.1 million or $0.37 per diluted share for the three months ended December 31, 2023 compared to a net loss of $3.3 million or $0.28 per diluted share for the three months ended December 31, 2022, and a net loss of $14.6 million or $1.15 per share for the year ended December 31, 2023, compared to a net loss of $12.1 million or $1.12 per diluted share for the year ended December 31, 2022 for the reasons previously mentioned.

The Company had 14,468,229 shares outstanding as of December 31, 2023.

**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, March 18, 2024
Time: 8:00 a.m. ET
Toll free (U.S. and International): 877-790-1503
Conference ID: 13744881

**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.

**Investor Contact:**
Acurx Pharmaceuticals, Inc.
David P. Luci, President & Chief Executive Officer Tel: 917-533-1469
Email: davidluci@acurxpharma.com

**ACURX PHARMACEUTICALS, INC.**
**BALANCE SHEETS**
**AS OF DECEMBER 31, 2023 and 2022**

| | December 31, 2023 | December 31, 2022 |
|---|---|---|
| ASSETS | | |
| CURRENT ASSETS | | |
| Cash | $ 7,474,188 | $ 9,111,751 |
| Other Receivable | 129,159 | — |
| Prepaid Expenses | 105,776 | 264,955 |
| TOTAL ASSETS | $ 7,709,123 | $ 9,376,706 |
| LIABILITIES AND SHAREHOLDERS' EQUITY | | |
| CURRENT LIABILITIES | | |
| Accounts Payable and Accrued Expenses | $ 3,042,438 | $ 2,061,685 |
| TOTAL CURRENT LIABILITIES | 3,042,438 | 2,061,685 |
| TOTAL LIABILITIES | 3,042,438 | 2,061,685 |
| COMMITMENTS AND CONTINGENCIES | | |
| SHAREHOLDERS' EQUITY | | |
| Common Stock; $.001 par value, 200,000,000 shares authorized, 14,468,229 and 11,627,609 shares issued and outstanding at December 31, 2023 and December 31, 2022, respectively | 14,468 | 11,628 |
| Additional Paid-In Capital | 57,871,070 | 45,944,478 |
| Accumulated Deficit | (53,218,853) | (38,641,085) |
| TOTAL SHAREHOLDERS' EQUITY | 4,666,685 | 7,315,021 |
| TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY | $ 7,709,123 | $ 9,376,706 |

**ACURX PHARMACEUTICALS, INC.**
**STATEMENTS OF OPERATIONS**
**YEARS ENDED DECEMBER 31, 2023 AND 2022**

| | Years Ended December 31, 2023 | 2022 |
|---|---|---|
| OPERATING EXPENSES | | |
| Research and Development | $ 6,043,597 | $ 4,754,271 |
| General and Administrative | 8,534,171 | 7,338,505 |
| TOTAL OPERATING EXPENSES | 14,577,768 | 12,092,776 |
| NET LOSS | $ (14,577,768) | $ (12,092,776) |
| LOSS PER SHARE | | |
| Basic and diluted net loss per common share | $ (1.15) | $ (1.12) |
| Weighted average common shares outstanding, basic and diluted | 12,671,572 | 10,816,412 |

View original content:https://www.prnewswire.com/news-releases/acurx-pharmaceuticals- inc-reports-fourth-quarter-and-full-year-2023-results-and-provides-business-update-302090837.html

SOURCE Acurx Pharmaceuticals, Inc.