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): September 6, 2023

Corvus Pharmaceuticals, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-37719**	**46-4670809**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

863 Mitten Road, Suite 102
Burlingame, California 94010
(Address of Principal Executive Offices) (Zip Code)

(650) 900-4520
(Registrant's telephone number, including area code)

(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(s)	Name of each exchange on which registered
Common Stock, Par Value $0.0001 per share	CRVS	Nasdaq Global Market

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 8.01. Other Events.

On September 6, 2023, Corvus Pharmaceuticals, Inc. (“Corvus” or the “Company”) issued a press release announcing the planned initiation of soquelitinib (CPI-818) Phase 3 registrational clinical trial in peripheral T cell lymphoma following its meeting with the U.S. Food and Drug Administration. A copy of the press release is being furnished herewith as Exhibit 99.1 to this Current Report on Form 8-K.

Item 9.01. Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Press release of Corvus Pharmaceuticals, Inc. dated September 6, 2023.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

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

Corvus Pharmaceuticals, Inc.

Date: September 7, 2023

By: /s/ Leiv Lea
Leiv Lea
Chief Financial Officer

Corvus Pharmaceuticals Confirms Planned Initiation of Soquelitinib (CPI-818) Phase 3 Registrational Clinical Trial in Peripheral T Cell Lymphoma Following Meeting with FDA

Plans to initiate soquelitinib potentially registrational Phase 3 clinical trial in Q1 2024

Company to host conference call and webcast tomorrow at 8:30 a.m. ET / 5:30 a.m. PT

BURLINGAME, Calif., Sept. 06, 2023 (GLOBE NEWSWIRE) -- Corvus Pharmaceuticals, Inc. (Nasdaq: CRVS), a clinical-stage biopharmaceutical company, confirmed today that it completed an End-of-Phase/Pre-Phase 3 meeting with FDA on its plans to initiate a Phase 3 registrational clinical trial of soquelitinib (formerly CPI-818), the Company's ITK inhibitor product candidate, in relapsed peripheral T cell lymphoma (PTCL).

“We are pleased with the outcome of our End-of-Phase/Pre-Phase 3 meeting with FDA, allowing us to advance ITK inhibition with soquelitinib into a potentially registrational clinical trial for patients with relapsed peripheral T cell lymphoma,” said Richard A. Miller, co-founder, president and chief executive officer of Corvus. “We appreciate the FDA’s input and their confirmation on the key aspects of the trial design, including sample size, dosing, eligibility, comparator arm and endpoints. We are now focused on finalizing the study protocol, qualifying trial sites and completing other standard steps required to initiate the trial. Based on current timelines, we anticipate that we can initiate the trial in the first quarter of 2024.”

The soquelitinib Phase 3 potentially registrational clinical trial is designed to enroll a total of 150 patients with relapsed PTCL that have received three or fewer prior therapies. Patients will be randomized 1:1 to soquelitinib 200 mg two-times a day or standard of care chemotherapy. The primary endpoint will be progression-free survival. Secondary endpoints will include objective response rate and overall survival. The Company is recruiting U.S. and international investigators and anticipates that leading academic and private medical centers with significant experience in lymphoma research will participate in the trial, including a principal investigator who has conducted other Phase 3 clinical trials in T cell lymphoma and authored many peer-reviewed articles on lymphomas.

Dr. Miller added, “Soquelitinib’s proposed mechanism of action, based on selective ITK inhibition, represents a platform opportunity with the potential to address a wide range of indications beyond hematologic cancers, including solid tumors and autoimmune/allergic diseases.”

Data highlighting the potential of selective inhibition of ITK to potentially enhance anti-tumor immune response to hematologic and solid tumors and provide a novel potential approach to cancer immunotherapy were recently published online as a preprint at bioRxiv.org. In addition, data demonstrating soquelitinib’s anti-tumor activity in patients with T cell lymphoma (TCL) and its therapeutic potential in Th2 and Th17-mediated autoimmune and allergic diseases was presented in a poster at the 64th American Society of Hematology (ASH) Annual Meeting & Exposition, which took place in December 2022. The preprint and ASH poster presentation are available on the Publications and Presentations page of the Corvus website.

Conference Call Details
Corvus will host a conference call and webcast tomorrow, Thursday, September 7, 2023, at 8:30 a.m. ET (5:30 a.m. PT), to discuss the soquelitinib Phase 3 clinical trial plan and other business updates. The conference call can be accessed by dialing 1-877-407-0784 (toll-free domestic) or 1-201-689-8560 (international) or by clicking on this link for instant telephone access to the event. The live webcast may be accessed via the investor relations section of the Corvus website. A replay of the webcast will be available on Corvus’ website for 90 days.

About Corvus Pharmaceuticals
Corvus Pharmaceuticals is a clinical-stage biopharmaceutical company pioneering the development of ITK inhibition as a new approach to immunotherapy for a broad range of cancer and immune diseases. The Company’s lead product candidate is soquelitinib, an investigational, oral, small molecule drug that selectively inhibits ITK and is planned to enter a Phase 3 potentially registrational clinical trial for patients with relapsed peripheral T cell lymphoma. Its other clinical-stage candidates are being developed for a variety of cancer indications. For more information, visit www.corvuspharma.com.

About Soquelitinib
Soquelitinib (CPI-818) is an investigational small molecule drug given orally designed to selectively inhibit ITK (interleukin-2-inducible T cell kinase), an enzyme that is expressed predominantly in T cells and plays a role in T cell and natural killer (NK) cell immune function. The immunologic effects of soquelitinib lead to what is known as Th1 skewing and is made possible by the high selectivity of soquelitinib for ITK. Research on soquelitinib’s mechanism of action suggests that it has the potential to control differentiation of normal T helper cells and enhance immune responses to tumors by augmenting the generation of cytotoxic killer T cells and the production of cytokines that inhibit cancer cell survival. Soquelitinib has been shown to prevent T cell exhaustion, a major limitation of current immunotherapy and CAR-T therapies. Optimal doses of soquelitinib have been shown to affect T cell differentiation and induce the generation of Th1 helper cells while blocking the development of both Th2 and Th17 cells and production of their secreted cytokines. Th1 T cells are required for immunity to tumors, viral infections and other infectious diseases. Th2 and Th17 helper T cells are involved in the pathogenesis of many autoimmune and allergic diseases. The Company believes the inhibition of specific molecular targets in T cells may be of therapeutic benefit for patients with cancers, including solid tumors, and in patients with autoimmune and allergic diseases. Based on interim results from a Phase 1/1b clinical trial in patients with refractory T cell lymphomas, which demonstrated tumor responses in very advanced,

refractory, difficult to treat T cell malignancies, the Company plans to initiate a potentially registrational Phase 3 clinical trial of soquelitinib in patients with relapsed peripheral T cell lymphoma (PTCL).

About Peripheral T Cell Lymphoma
Peripheral T cell lymphoma (PTCL) is a heterogeneous group of malignancies accounting for about 10% of non-Hodgkin's lymphomas (NHL) in Western populations, reaching 20% to 25% of NHL in some parts of Asia and South America. The most common subtypes are PTCL-not otherwise specified (PTCL-NOS) and T follicular helper cell lymphoma. Initial therapy for these diseases is typically combination chemotherapy, however, approximately 75% of patients either do not respond or relapse within the first two years. Patients in relapse are treated with various chemotherapy agents but have poor overall outcomes with median progression-free survival in the 3 to 4 month range and overall median survival of 6 to 12 months. There are no approved drugs in relapsed PTCL based on randomized trials.

PTCL is a disease of mature helper T cells that express ITK, often containing numerous genetic mutations and frequently associated with viral infection. Most often the malignant cells of PTCL express a Th2 phenotype.

Forward-Looking Statements
This press release contains forward-looking statements, including statements related to the potential safety and efficacy of the Company's product candidates including soquelitinib and ciforadenant; the potential use of soquelitinib to treat a variety of solid tumors and hematological cancers as well as autoimmune/allergic diseases; the Company's ability and its partners' ability, as well as the timing thereof, to develop and advance product candidates through and successfully complete preclinical studies and clinical trials, including the Company's Phase 1/1b clinical trial of soquelitinib and its potentially registrational Phase 3 clinical trial for soquelitinib; the timing and its ability to launch clinical trials including the potentially registrational Phase 3 clinical trial for soquelitinib; and clinical trial designs and plans. All statements other than statements of historical fact contained in this press release are forward-looking statements. These statements often include words such as "believe," "expect," "anticipate," "intend," "plan," "estimate," "seek," "will," "may" or similar expressions. Forward-looking statements are subject to a number of risks and uncertainties, many of which involve factors or circumstances that are beyond the Company's control. The Company's actual results could differ materially from those stated or implied in forward-looking statements due to a number of factors, including but not limited to, risks detailed in the Company's Quarterly Report on Form 10-Q for the three months ended June 30, 2023, filed with the Securities and Exchange Commission on August 8, 2023, as well as other documents that may be filed by the Company from time to time with the Securities and Exchange Commission. In particular, the following factors, among others, could cause results to differ materially from those expressed or implied by such forward-looking statements: the Company's ability to demonstrate sufficient evidence of efficacy and safety in its clinical trials of soquelitinib and its other product candidates; the accuracy of the Company's estimates relating to its ability to initiate and/or complete preclinical studies and clinical trials and release data from such studies and clinical trials; the results of preclinical studies and interim data from clinical trials not being predictive of future results; the Company's ability to enroll sufficient numbers of patients in its clinical trials; the unpredictability of the regulatory process; regulatory developments in the United States, and other foreign countries; the costs of clinical trials may exceed expectations; and the Company's ability to raise additional capital. Although the Company believes that the expectations reflected in the forward-looking statements are reasonable, it cannot guarantee that the events and circumstances reflected in the forward-looking statements will be achieved or occur, and the timing of events and circumstances and actual results could differ materially from those projected in the forward-looking statements. Accordingly, you should not place undue reliance on these forward-looking statements. All such statements speak only as of the date made, and the Company undertakes no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

INVESTOR CONTACT:
Leiv Lea
Chief Financial Officer
Corvus Pharmaceuticals, Inc.
+1-650-900-4522
llea@corvuspharma.com

MEDIA CONTACT:
Sheryl Seapy
Real Chemistry
+1-949-903-4750
sseapy@realchemistry.com