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): January 13, 2025

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, CA** **(Address of principal executive offices)**	**94010** **(Zip Code)**

Registrant's telephone number, including area code: (650) 900-4520
Former name or former address, if changed since last report: Not applicable

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 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2). 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 7.01. Regulation FD.

On January 13, 2025, Corvus Pharmaceuticals, Inc. (the "Company") issued the press release furnished as Exhibit 99.1 hereto.

Item 8.01. Other Events.

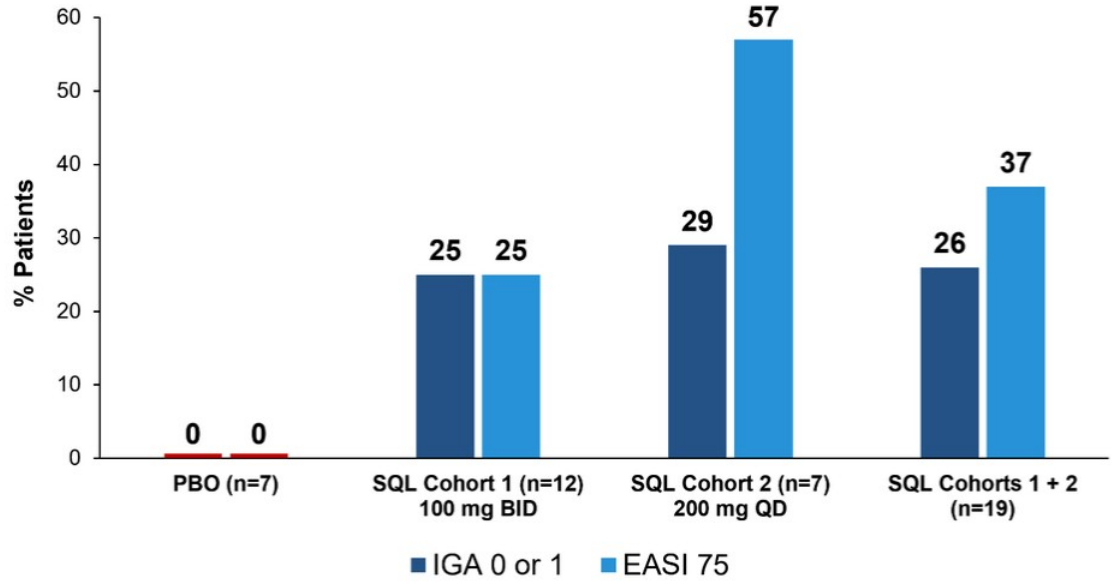
On January 13, 2025, the Company announced new interim data from the randomized, double-blind, placebo-controlled Phase 1 clinical trial evaluating soquelitinib in patients with moderate to severe atopic dermatitis.

Soquelitinib Interim Data from the Atopic Dermatitis Phase 1 Clinical Trial

The Company is reporting results from 16 patients in Cohort 1 (12 patients in the soquelitinib group receiving 100 mg orally twice per day vs. four receiving placebo) and 10 patients in Cohort 2 (seven patients in the soquelitinib group receiving 200 mg orally once per day vs. three receiving placebo) for which 28 days of treatment have been completed. For those 19 patients in the soquelitinib group, 26% achieved IGA 0 or 1 and 37% achieved EASI 75; and of the seven in the placebo group, none achieved IGA 0 or 1 or EASI 75 (see Figure 1 below). IGA 0 or 1 and EASI 75 have been determined by the U.S. Food and Drug Administration (FDA) to be clinically meaningful and approvable endpoints and have been the endpoints used in clinical trials for other FDA approved treatments for atopic dermatitis.

No significant safety issues were observed and no clinically significant laboratory abnormalities were seen. All 10 patients from Cohort 2 completed 28 days of dosing at the full dose of 200 mg orally once per day; the remaining patients from Cohort 2 are at various stages of treatment. Cohort 2 of the trial is fully enrolled (N=16) and the Company plans to report full results from all four study cohorts in the second quarter 2025.

Figure 1: Percent Patients Achieving Endpoints IGA 0 or 1, EASI 75 at Day 28 of Treatment



The placebo patients from Cohort 1 (n=4) and Cohort 2 (n=3) are combined.

Soquelitinib Atopic Dermatitis Phase 1 Clinical Trial Design

The randomized, double-blind, placebo-controlled Phase 1 clinical trial is planned to enroll 64 patients with moderate to severe atopic dermatitis that previously failed one prior topical or systemic therapy. Patients are enrolled into one of four dosing cohorts in a 3:1 ratio (12 active and four placebo) to receive either soquelitinib or placebo. The cohorts are

sequentially enrolled and will examine 100 mg orally twice per day, 200 mg orally once per day, 200 mg orally twice per day and 400 mg orally once per day. Patients are treated for 28 days and are then followed for an additional 30 days with no therapy.

These doses were selected based on the Company's prior experience evaluating soquelitinib in T cell lymphoma patients. The doses in the atopic dermatitis trial studied in Cohorts 1 and 2 are lower than the 200 mg orally twice a day dosing regimen, which is the level that has been shown to provide complete ITK occupancy and that is being evaluated in the Company's ongoing registrational Phase 3 clinical trial of soquelitinib in peripheral T cell lymphoma.

The primary endpoints include safety and tolerability. Efficacy, measured by improvement in EASI score and IGA, are secondary endpoints. Reduction in itch and various cytokine biomarkers are exploratory endpoints. EASI scores are also evaluated by the percent of patients that achieve a specified percent reduction in EASI score – EASI 50 for patients that achieved a 50% reduction; EASI 75 for a 75% reduction; and EASI 90 for a 90% reduction. Corvus and a data monitoring committee monitor the data from the trial as the trial progresses.

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements, including statements related to the potential safety and efficacy of soquelitinib; and the Company's conduct of, enrollment in and timing of clinical trials and results. All statements other than statements of historical fact contained in this Current Report on Form 8-K 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 September 30, 2024, filed with the Securities and Exchange Commission on November 12, 2024, 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 its 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.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release of Corvus Pharmaceuticals, Inc. dated January 13, 2025.
104	Cover Page Interactive Data File (the cover page XBRL tags are embedded within the Inline XBRL Document).

The information furnished in Exhibit 99.1 shall not be deemed "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 into any other filing under the Exchange Act or the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such a filing.

SIGNATURES

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

CORVUS PHARMACEUTICALS, INC.

Date: January 13, 2025

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

Corvus Pharmaceuticals Announces Data from Cohort 2 of Placebo-Controlled Phase 1 Clinical Trial of Soquelitinib for Atopic Dermatitis

Data continue to demonstrate a favorable safety and efficacy profile, including improvements in IGA 0 or 1 and EASI 75 scores compared to placebo

BURLINGAME, Calif., January 13, 2025 - Corvus Pharmaceuticals, Inc. (NASDAQ: CRVS), a clinical-stage biopharmaceutical company, today announced new interim data from the randomized, double-blind, placebo-controlled Phase 1 clinical trial evaluating soquelitinib in patients with moderate to severe atopic dermatitis. The data, which include previously reported results from cohort 1 of the trial and new data covering 10 patients with 28-day follow-up from cohort 2 of the trial, demonstrated a favorable safety profile and efficacy profile. This includes significant responses in the soquelitinib treatment groups compared to placebo for clinically significant endpoints of IGA (Investigator Global Assessment) 0 or 1 and EASI (Eczema Area and Severity Index) 75.

“As we increase the number of patients, we remain excited by the outlook for our Phase 1 clinical trial of soquelitinib for the treatment of atopic dermatitis,” said Richard A. Miller, M.D., co-founder, president and chief executive officer of Corvus. “These additional data from cohort 2 evaluating a 200 mg once a day dose appear better than the initial results from cohort 1 reported in December. Using rigorous efficacy endpoints of IGA 0 or 1 and EASI 75, we see clinically meaningful activity of soquelitinib in both cohorts compared to the placebo group, which had no patients achieve these endpoints after four weeks of treatment. We focus on these endpoints because they have been accepted as measurements of clinical benefit and have been used as the basis for regulatory approval for several approved treatments for atopic dermatitis.”

Dr. Miller added, “Based on the results to-date, we believe soquelitinib will be attractive to physicians and patients due to its convenient oral administration, safety and novel mechanism of action. It also is well positioned as a potential new treatment option for a broad range of immune disease indications based on its ability to modulate and control parallel signaling pathways in the immune system. We look forward to completing enrollment in the atopic dermatitis trial and reporting full results in the second quarter 2025 while also continuing to advance our Phase 3 registration trial in relapsed peripheral T cell lymphoma and other clinical programs.”

Soquelitinib New Interim Data from the Atopic Dermatitis Phase 1 Clinical Trial

The Company is reporting results from 16 patients in Cohort 1 (12 patients in the soquelitinib group receiving 100 mg orally twice per day vs. four receiving placebo) and 10 patients in Cohort 2 (seven patients in the soquelitinib group receiving 200 mg orally once per day vs. three receiving placebo) for which 28 days of treatment have been completed. For those 19 patients in the soquelitinib group, 26% achieved IGA 0 or 1 and 37% achieved EASI 75; and of the seven in the placebo group, none achieved IGA 0 or 1 or EASI 75 (see Figure 1 below). IGA 0 or 1 and EASI 75 have been determined by the U.S. Food and Drug Administration (FDA) to be clinically meaningful and approvable endpoints and have been the endpoints used in clinical trials for other FDA approved treatments for atopic dermatitis.

No significant safety issues were observed and no clinically significant laboratory abnormalities were seen. All 10 patients from Cohort 2 completed 28 days of dosing at the full dose of 200 mg orally once per day; the remaining patients from Cohort 2 are at various stages of treatment. Cohort 2 of the trial is fully enrolled (N=16) and the Company plans to report full results from all four study cohorts in the second quarter 2025.

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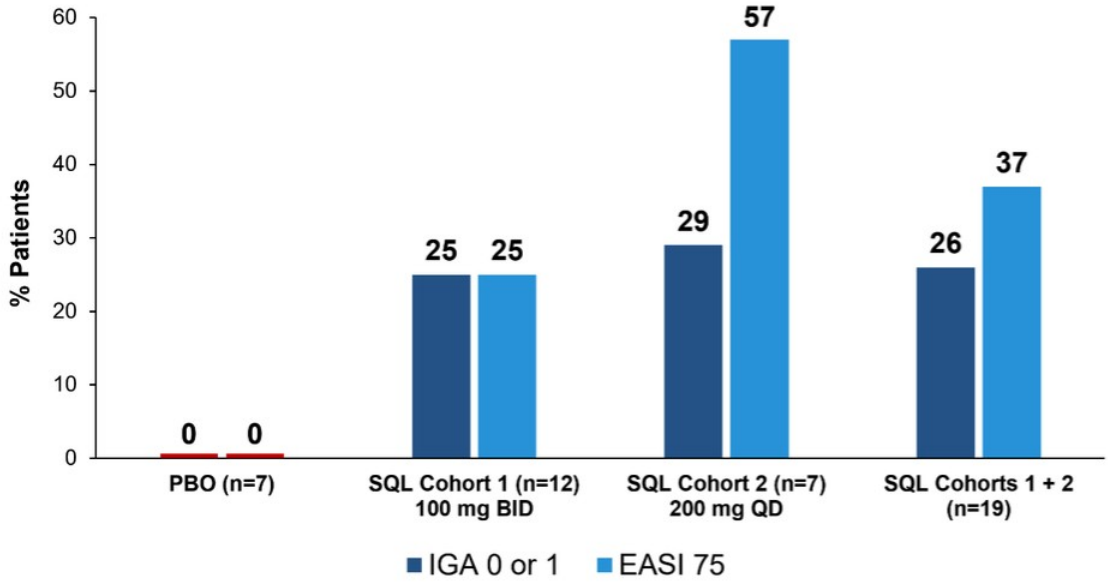

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Soquelitinib Atopic Dermatitis Phase 1 Clinical Trial Design

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These doses were selected based on the Company's prior experience evaluating soquelitinib in T cell lymphoma patients. The doses in the atopic dermatitis trial studied in Cohorts 1 and 2 are lower than the 200 mg orally twice a day dosing regimen, which is the level that has been shown to provide complete ITK occupancy and that is being evaluated in the Company's ongoing registrational Phase 3 clinical trial of soquelitinib in peripheral T cell lymphoma.

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Upcoming Presentation and Webcast
Dr. Miller will present a corporate overview including the new data from Cohort 2 of the soquelitinib Phase 1 clinical trial at the 43rd Annual J.P. Morgan Healthcare Conference on Wednesday, January 15 at 2:15 pm ET / 11:15 am PT. An audio webcast of the presentation will be available live and for 30 days following the event. The webcast may be accessed via the investor relations section of the Corvus website.

About Atopic Dermatitis
Atopic dermatitis, also called eczema, is a chronic disease that can cause inflammation, redness, scaly patches, blisters and irritation of the skin. It affects up to 20% of children and up to 10% of adults, and treatments include topical therapies, oral therapies and systemic injectable biologic therapies. It is frequently associated with other allergic disorders such as food allergies and asthma. Atopic dermatitis, like asthma and allergy, involves the participation of Th2 lymphocytes which secrete cytokines that result in inflammation. Soquelitinib has been shown in preclinical studies to inhibit cytokine production from Th2 lymphocytes.

About Soquelitinib
Soquelitinib (formerly 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. Soquelitinib has 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. Recent studies have demonstrated that ITK controls a switch between the differentiation of Th17 proinflammatory cells and T regulatory suppressor cells. Inhibition of ITK leads to a shift toward T regulatory cell differentiation which has the potential to suppress autoimmune and inflammatory reactions. 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 has initiated a registrational Phase 3 clinical trial (NCT06561048) of soquelitinib in patients with relapsed PTCL. Soquelitinib is also now being investigated in a randomized placebo-controlled phase 1 clinical trial in patients with atopic dermatitis. A recent publication describing the chemistry, enzymology and biology of soquelitinib appeared in npj Drug Discovery in December 2024 and is available online at the Nature website and on the Publications and Presentations page of the Corvus website.

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. Its other clinical-stage candidates are being developed for a variety of cancer indications. For more information, visit www.corvuspharma.com.

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; the outlook for the Phase 1 clinical trial of soquelitinib; physician and patient receptivity to soquelitinib; the potential use of soquelitinib to treat atopic dermatitis and other immune diseases; the Company's conduct of, enrollment in and timing of clinical trials and results, including the Company's Phase 3 clinical trial in PTCL and Phase 1 clinical trial in atopic dermatitis; and the potential of ITK inhibition as a new approach to immunotherapy. 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 September 30, 2024, filed with the Securities and Exchange Commission on November 12, 2024, 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 its 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