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): November 7, 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 2.02. Results of Operations and Financial Condition.

On November 7, 2023, Corvus Pharmaceuticals, Inc. issued a press release regarding, among other matters, its financial results for the three and nine months ended September 30, 2023 and its financial position as of September 30, 2023, and provided a business update. A copy of the press release is furnished as Exhibit 99.1 to this Form 8-K.

Item 9.01. Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Press release of Corvus Pharmaceuticals, Inc. dated November 7, 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: November 7, 2023

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

EXHIBIT 99.1

Corvus Pharmaceuticals Provides Business Update and Reports Third Quarter 2023 Financial Results

Protocol finalized for soquelitinib (CPI-818) Phase 3 registrational clinical trial in peripheral T cell lymphoma (PTCL); multiple sites preparing to initiate trial enrollment

New data from soquelitinib Phase 1 T cell lymphoma trial accepted for presentation at the 65th ASH Annual Meeting and Exposition

New publications highlight therapeutic potential of ITK inhibition in solid tumors and multiple autoimmune and allergic conditions

Conference call today at 4:30 p.m. ET / 1:30 p.m. PT

BURLINGAME, Calif., Nov. 07, 2023 (GLOBE NEWSWIRE) -- Corvus Pharmaceuticals, Inc. (Corvus or the Company) (Nasdaq: CRVS), a clinical-stage biopharmaceutical company, today provided a business update and reported financial results for the third quarter ended September 30, 2023.

“We continue to make progress towards initiating our Phase 3 registrational clinical trial for soquelitinib, including finalizing the study protocol and submitting it to the FDA,” said Richard A. Miller, M.D., co-founder, president and chief executive officer of Corvus. “From a regulatory standpoint, we are clear to initiate the trial. We are delighted by the strong interest from leading academic centers in the U.S. in participating in the clinical trial, which is anticipated to begin enrolling patients by the second quarter 2024. We also plan to initiate a Phase 2 trial in early 2024 with soquelitinib monotherapy in recurrent renal cell cancer and have been encouraged by recent work from other academic groups demonstrating the potential of ITK inhibition in solid tumor animal models. In addition, our internal research team continues to reveal the therapeutic potential of ITK inhibition in several preclinical models of autoimmune and allergic disease, including the inhibition of Th17 cells and secretion of IL-17, which are validated mediators of inflammatory disease.”

Business Update and Strategy

Prioritized Program: Soquelitinib (formerly CPI-818, Corvus’ selective ITK inhibitor)

Soquelitinib for T Cell Lymphoma

- Corvus continues to enroll patients with relapsed PTCL in a Phase 1/1b clinical trial evaluating single agent therapy with soquelitinib. The latest data from the trial was reported at the International Conference on Malignant Lymphoma, which took place June 13-17, 2023 in Lugano, Switzerland. As of the May 18, 2023 cut-off date, the data showed that a majority of the patients treated with the optimal dose of 200 mg twice per day of soquelitinib experienced tumor regression.
- New interim data from the Phase 1/1b clinical trial, along with complementary preclinical data, will be presented in a poster presentation at the 65th American Society of Hematology (ASH) Annual Meeting and Exposition in December 2023.

Soquelitinib Preclinical Data in Hematologic and Solid Tumors

- In July 2023, Corvus announced the publication of preclinical data on soquelitinib as a preprint at bioRxiv, which highlighted the selective inhibition of ITK being able to potentially enhance anti-tumor immune response to hematologic and solid tumors, indicating its potential as a novel approach to cancer immunotherapy.
- In September 2023, a paper was published by an independent academic group in Scientific Reports validating the potential of ITK inhibition for treatment of solid tumors. The preclinical data demonstrated a reduction and reversal of T cell exhaustion markers and an increase in the infiltration of killer T cells into tumors, consistent with soquelitinib’s proposed mechanism of action. The paper highlights the potential of selective ITK inhibition for the treatment of cancers and helps to confirm preclinical and clinical results generated by Corvus.

Soquelitinib Preclinical Data in Autoimmune/Allergy

- On November 1, 2023, 2023, Corvus announced the publication of preclinical data on soquelitinib as a preprint at bioRxiv that demonstrated ITK’s selective inhibition which produced therapeutic benefits in several autoimmune and allergy preclinical models including psoriasis, asthma, pulmonary fibrosis, scleroderma and graft versus host disease. The mechanism of action involves the inhibition of Th2 and Th17 cells and the subsequent production of cytokines such as IL-17, IL-4, IL-5 and other cytokines involved in these diseases. The novel mechanism is a result of ITK inhibition and blockade of formation of Th2 and Th17 cells.

Partner Led Programs: Ciforadenant (adenosine 2a receptor inhibitor) and Mupadolimab (anti-CD73)

- The Kidney Cancer Research Consortium is enrolling a Phase 1b/2 clinical trial evaluating ciforadenant as a potential first line therapy for metastatic renal cell cancer (RCC) in combination with ipilimumab (anti-CTLA-4) and nivolumab (anti-PD-1). The Phase 1b portion of this trial has been completed and patients are now being enrolled in the Phase 2 portion. The clinical trial is expected to enroll up to 60 patients and initial data is anticipated in early 2024.

- Angel Pharmaceuticals, Corvus' partner in China, is enrolling patients in a Phase 1/1b clinical trial of mupadolimab in patients with non-small cell lung cancer (NSCLC) and head and neck squamous cell cancers. In this clinical trial, patients will receive mupadolimab monotherapy or in combination with pembrolizumab.

Financial Results
As of September 30, 2023, Corvus had cash, cash equivalents and marketable securities of $32.2 million as compared to $42.3 million as of December 31, 2022. During the nine months ending September 30, 2023, the Company sold 2,461,903 shares of its common stock through its at-the-market program, generating net proceeds to the Company of approximately $7.8 million. Corvus expects full year 2023 net cash used in operating activities to be between approximately $22 million and $23 million, resulting in a projected cash balance of between $27 million and $28 million as of December 31, 2023. Based on its current plans, Corvus expects its cash to fund operations into late 2024.

Research and development expenses for the three months ended September 30, 2023 totaled $4.0 million compared to $10.4 million for the same period in 2022. The decrease of $6.4 million was primarily due to lower clinical trial and manufacturing costs associated with the development of mupadolimab.

The net loss for the three months ended September 30, 2023 was $6.0 million compared to a net loss of $14.8 million for the same period in 2022. Total stock compensation expense for the three months ended September 30, 2023 was $0.5 million compared to $0.7 million for the same period in 2022 and the non-cash loss from Corvus' equity method investment in Angel Pharmaceuticals was $0.9 million for the three months ended September 30, 2023 compared to $2.7 million in the same period in 2022.

Conference Call Details
Corvus will host a conference call and webcast today, Tuesday, November 7, 2023, at 4:30 p.m. ET (1:30 p.m. PT), during which time management will provide a business update and discuss the third quarter 2023 financial results. The conference call can be accessed by dialing 1-855-327-6837 (toll-free domestic) or 1-631-891-4304 (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. Corvus plans to initiate a Phase 3 registrational clinical trial for soquelitinib in 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 also 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 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 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. First line treatment 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 three to four month range and overall median survival of six 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.

About Ciforadenant
Ciforadenant (CPI-444) is an investigational small molecule, oral, checkpoint inhibitor designed to disable a tumor's ability to subvert attack by the immune system by blocking the binding of adenosine to immune cells present in the tumor microenvironment. Adenosine, a metabolite of ATP (adenosine tri-phosphate), is produced within the tumor microenvironment

where it may bind to the adenosine A2A receptor present on immune cells and block their activity. Ciforadenant has been shown to block the immunosuppressive effects of myeloid cells present in tumors and preclinical studies published in 2018 demonstrated synergy with combinations of anti PD1 and anti-CTLA4 antibodies.

About Mupadolimab
Mupadolimab (CPI-006) is an investigational, potent humanized monoclonal antibody that is designed to react with a specific site on CD73. In preclinical studies, it has demonstrated immunomodulatory activity resulting in activation of lymphocytes, induction of antibody production from B cells and effects on lymphocyte trafficking. While there are other anti-CD73 antibodies and small molecules in development for treatment of cancer, such agents react with a different region of CD73. Mupadolimab is designed to react with a region of the molecule that acts to stimulate B cells and block production of immunosuppressive adenosine. Mupadolimab is being studied in combination with pembrolizumab in a Phase 1b/2 clinical trial in patients with advanced head and neck cancers and in patients with NSCLC that have failed chemotherapy and anti-PD(L)1 therapy. It is postulated that the activation of B cells will enhance immunity within the tumors of these patients, leading to improved clinical outcomes.

About Angel Pharmaceuticals
Angel Pharmaceuticals is a privately held biopharmaceutical company developing a pipeline of precisely targeted investigational medicines for cancer, autoimmune, infectious and other serious diseases in China. Angel Pharmaceuticals was launched through a collaboration with U.S.-based Corvus and investments from investors in China. Angel Pharmaceuticals licensed the rights to develop and commercialize Corvus' three clinical-stage candidates – soquelitinib, ciforadenant and mupadolimab – in greater China and obtained global rights to Corvus' BTK inhibitor preclinical programs. Under the collaboration, Corvus currently has a 49.7% equity stake in Angel Pharmaceuticals excluding 7% of Angel's equity reserved for issuance under the Angel ESOP, and Corvus has designated three individuals on Angel's five-person Board of Directors. For more information, visit www.angelpharma.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, ciforadenant and mupadolimab; the potential use of soquelitinib to treat a variety of solid tumors and hematological cancers; the Company's ability and its partners' ability, as well as the timing thereof, to develop and advance product candidates into and successfully complete preclinical studies and clinical trials, including the Company's Phase 1/1b clinical trial of soquelitinib and its Phase 1b/2 clinical trial of ciforadenant; the timing of and the Company's ability to launch clinical trials including the potentially registrational Phase 3 clinical trial for soquelitinib; the timing of initial data from the Phase 1b/2 clinical trial with ciforadenant; the timing of and the Company's ability to secure institutional review board approvals for its Phase 3 trial for soquelitinib; and the estimated amount of net cash used in operating activities for 2023 and its ability to fund operations into late 2024. 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, 2023, filed with the Securities and Exchange Commission on or about the date hereof, 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; the Company's ability to accurately estimate the amount of net cash used in operating activities for 2023 and cash on hand providing funding into late 2024 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. The Company's results for the quarter ended September 30, 2023 are not necessarily indicative of its operating results for any future periods.

CORVUS PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
	(unaudited)		(unaudited)	
Operating expenses:				

Research and development	$ 3,965	$ 10,365	$ 12,527	$ 20,388
General and administrative	1,595	2,108	5,229	6,511
Total operating expenses	5,560	12,473	17,756	26,899
Loss from operations	(5,560)	(12,473)	(17,756)	(26,899)
Interest income and other expense, net	425	225	1,204	336
Sublease income - related party	—	147	56	439
Loss from equity method investment	(865)	(2,730)	(3,880)	(5,367)
Net loss	$ (6,000)	$ (14,831)	$ (20,376)	$ (31,491)
Net loss per share, basic and diluted	$ (0.12)	$ (0.32)	$ (0.43)	$ (0.68)
Shares used to compute net loss per share, basic and diluted	48,971,246	46,553,511	47,683,792	46,553,511

CORVUS PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands)

	September 30, 2023	December 31, 2022
	(unaudited)	
Assets		
Cash, cash equivalents and marketable securities	$ 32,168	$ 42,303
Operating lease right-of-use asset	1,423	2,217
Other assets	1,279	1,843
Investment in Angel Pharmaceuticals	17,072	21,877
Total assets	$ 51,942	$ 68,240
Liabilities and stockholders' equity		
Accounts payable and accrued liabilities and other liabilities	$ 5,963	$ 9,524
Operating lease liability	1,690	2,601
Stockholders' equity	44,289	56,115
Total liabilities and stockholders' equity	$ 51,942	$ 68,240

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