

**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 28, 2023

Corvus Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or Other Jurisdiction of Incorporation)

001-37719

(Commission File Number)

46-4670809

(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 March 28, 2023, Corvus Pharmaceuticals, Inc. issued a press release regarding, among other matters, its financial results for the fourth quarter and full year ended December 31, 2022 and its financial position as of December 31, 2022, and provided a business update. A copy of the press release is furnished as Exhibit 99.1 to this Form 8-K.

The information in this Item 2.02 of this Form 8-K and the Exhibit 99.1 attached hereto 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, or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

Exhibit No. Description

[99.1](#) [Press release of Corvus Pharmaceuticals, Inc. dated March 28, 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: March 28, 2023

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

Corvus Pharmaceuticals Provides Business Update and Reports Fourth Quarter and Full Year 2022 Financial Results

New CPI-818 Predictive Biomarker Enables Selection of Lymphoma Patients Most Likely to Benefit from Treatment

Conference Call Today at 4:30 p.m. ET / 1:30 p.m. PT

BURLINGAME, Calif., March 28, 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 fourth quarter and year ended December 31, 2022.

“Heading into 2023, we are building momentum for CPI-818, our ITK inhibitor, which we believe is well positioned to provide a platform opportunity across cancer and immune diseases,” said Richard A. Miller, M.D., co-founder, president and chief executive officer of Corvus. “This includes a growing body of clinical and preclinical data supporting ITK inhibition across a range of indications. The most encouraging data is in oncology, where enrollment in our Phase 1/1b trial in T cell lymphoma has accelerated and has enabled us both to increase the number of patients treated at the optimum dose and to identify a predictive biomarker that we believe will enrich for patients most likely to benefit from treatment with CPI-818. Looking forward, we are focused on achieving value driving milestones for CPI-818 including interim T cell lymphoma clinical data at upcoming medical meetings and additional preclinical data with CPI-818 in solid tumors at the upcoming AACR meeting in April. In addition, we have upside potential from ciferadenant and mupadolimab, the clinical development of which are primarily being advanced and funded by partners.”

Business Update and Strategy

Prioritized Program: CPI-818 (selective ITK inhibitor)

CPI-818 for T Cell Lymphoma

- CPI-818 Phase 1/1b clinical trial results presented at the 64th American Society of Hematology (ASH) Annual Meeting & Exposition in December 2022 provided clinical data and *in vivo* evidence supporting its ongoing development as a therapy for T cell lymphoma and its potential in autoimmune and allergic diseases. Key data from the presentation include:
 - As of September 2, 2022, there were 1 complete response (CR), 1 nodal CR and 2 partial responses (PR) in 11 evaluable patients in the 200 mg twice per day cohort (identified optimal dose). An additional PR was seen in a patient receiving the 600 mg twice per day dose. No dose limiting toxicities were observed in 43 patients enrolled across four dosing cohorts, and a maximally tolerated dose was not reached at doses as high as 600 mg twice per day.
 - The 200 mg dose was shown to induce Th1 skewing and both Th2 and Th17 blockade based on findings in peripheral blood samples from several patients and *in vitro* data demonstrated that it did so in a dose-dependent manner that supported the selection of the 200 mg twice per day optimum dose. The findings of the human and preclinical studies suggest that CPI-818 enhances anti-tumor immunity representing a potentially novel approach to immunotherapy.
- Enrollment in the 200 mg cohort has accelerated and is ongoing. As of February 23, 2023, 20 patients were enrolled, including 13 evaluable for tumor response. There have been 1 CR of 24 months duration, 1 equivocal CR awaiting confirmatory PET scan of 13+ months duration (a previous PR), 1 nodal CR of 21 months duration and 1 PR of 7 months duration. Ten patients continue on therapy, including seven that have not yet been evaluated for tumor response. The swimmer and waterfall tumor plots for these patients are shown below.
- **New CPI-818 predictive biomarker:** Corvus has identified a biomarker associated with response to CPI-818. CPI-818 induces a host anti-tumor cell mediated immune response that requires normal functioning T cells. Data from the 200 mg cohort in the Phase 1/1b clinical trial indicates that a minimum absolute lymphocyte count (ALC) above 900 per cubic milliliter of blood is required for tumor response and disease control. Four of eight patients with ALC above 900 have objective responses (those four patients are described above), all eight have disease control (stable disease, PR, CR) and the median progression free survival (PFS) is 28.1 months. No objective responses were seen in five patients (0 of 5) with ALC below 900 and the PFS is 2.1 months. The ALC biomarker is routinely measured, is consistent with CPI-818’s presumed mechanism of action and is present in about 70% of patients based on the Company’s experience to-date. This biomarker has been incorporated as an eligibility criterion in the ongoing Phase 1/1b clinical trial.

Figure 1: Swimmer Plot for Patients in the 200 mg Dose Cohort of the CPI-818 Phase 1/1b Clinical Trial for T Cell Lymphoma. The plot shows the tumor response and duration (months) for patients with various tumor histologies, which are shown on the chart and defined as follows: PTCL-NOS, peripheral T cell lymphoma not otherwise specified; CTCL-SS, cutaneous T cell lymphoma Sezary; CTCL-MF, cutaneous T cell lymphoma mycosis fungoides; AITL, angioimmunoblastic T cell lymphoma; ALCL, anaplastic T cell lymphoma and NKTCL, natural killer T cell lymphoma. The tumor response evaluation are labeled on the chart and are defined as follows: CR, complete response; equivocal CR; PR, partial response; SD, stable disease; PD, progressive disease. Arrows indicate that treatment with CPI-818 is continuing as of the February 23, 2023 data cut-off.

Figure 2: Waterfall Plot for Patients in the 200 mg Dose Cohort of the CPI-818 Phase 1/1b Clinical Trial for T Cell Lymphoma. The plot shows the best percent change in tumor volume in the evaluable patients from the same group shown in Figure 1.

- Corvus recently received a communication from the U.S. Food and Drug Administration (FDA) regarding its clinical development plans for CPI-818. Based on the current enrollment rate of its ongoing Phase 1/1b clinical trial, the Company believes that the number of patients treated in this clinical trial would provide adequate safety and preliminary efficacy data to inform the design of a registration Phase 3 randomized clinical trial. As recommended by the FDA, the Company plans to meet with the FDA to discuss such a clinical trial; it is anticipated that this meeting will take place later this year.

Reprioritization of CPI -818 for Atopic Dermatitis

- Based on recent progress and data supporting the ongoing development of CPI-818 for T cell lymphoma and other cancers, Corvus has decided to delay its plans to initiate a Phase 1 clinical trial in atopic dermatitis. This decision allows the Company to conserve cash and intensify its focus on T cell lymphoma, which could include conducting a potentially registrational, randomized Phase 3 trial. While Corvus is pausing development of CPI-818 for the treatment of atopic dermatitis, the Company will continue to investigate the potential role of CPI-818 in immune diseases through its ongoing and planned preclinical research and external collaborations.

CPI-818 for HIV

- In February 2023, researchers from The University of California San Francisco-Bay Area Center for AIDS Research (UCSF) presented new data at the 30th Annual Conference on Retroviruses and Opportunistic Infections demonstrating the potential of CPI-818 to reduce the need for chronic human immunodeficiency virus (HIV) therapy. The data further highlights the broad therapeutic opportunity for ITK inhibition with CPI-818. Based on this positive data, the UCSF team plans to continue studying the potential for ITK inhibition to be developed within antiproliferative and “block-and-lock” HIV cure strategies.

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

- The Kidney Cancer Research Consortium (KCRC) 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 clinical trial is expected to enroll up to 60 patients and initial data is anticipated before the end of 2023.
- 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 December 31, 2022, Corvus had cash, cash equivalents and marketable securities totaling \$42.3 million. This compared to cash, cash equivalents and marketable securities of \$69.5 million as of December 31, 2021. Corvus expects full year 2023 net cash used in operating activities to be between approximately \$19 million and \$22 million, resulting in a projected cash balance of between \$20 million and \$23 million as of December 31, 2023. Based on its current plans, Corvus expects its cash to fund operations into 2024.

Research and development expenses for the three months and full year ended December 31, 2022 totaled \$4.1 million and \$24.5 million, respectively, compared to \$4.8 million and \$29.1 million for the same periods in 2021. In the fourth quarter of 2022, the decrease of \$0.7 million was primarily related to a decrease in personnel costs.

The net loss for the three months ended December 31, 2022 was \$9.8 million compared to a net loss of \$9.2 million for the same period in 2021. Total stock compensation expense for the three months ended December 31, 2022 was \$0.6 million compared to \$0.7 million for the same period in 2021 and the non-cash loss from the Company’s equity method investment in Angel Pharmaceuticals was \$4.6 million for the three months ended December 31, 2022 compared to \$2.6 million for the same period in 2021.

Conference Call Details

Corvus will host a conference call and webcast today, Tuesday, March 28, 2023, at 4:30 p.m. ET (1:30 p.m. PT), during which time management will provide a business update and discuss the fourth quarter and full year 2022 financial results. The conference call can be accessed by dialing 1-844-825-9789 (toll-free domestic) or 1-412-317-5180 (international) or by clicking on this link and requesting a return call and using the conference passcode 3154152. 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. Corvus’ lead product candidate is CPI-818, an investigational, oral, small molecule drug that selectively inhibited ITK in preclinical studies and is in a multicenter Phase 1/1b clinical trial in patients with several types of T cell lymphomas. The Company’s second clinical program, ciforadenant (CPI-444), is an oral, small molecule inhibitor of the A2A receptor that is in an open-label Phase 1b/2 clinical trial. Its third clinical program,

mupadolimab (CPI-006), is a humanized monoclonal antibody directed against CD73 that has exhibited immunomodulatory activity and activation of immune cells in preclinical and clinical studies. For more information, visit www.corvuspharma.com.

About CPI-818

CPI-818 is an investigational small molecule drug given orally that has selectively inhibited ITK (interleukin-2-inducible T cell kinase) in preclinical studies. It was designed to block malignant T cell growth and to modulate immune responses. ITK, an enzyme, is expressed predominantly in T cells and plays a role in T cell and natural killer (NK) cell lymphomas and leukemias, as well as in normal immune function. Recent clinical data in T cell lymphomas suggests that CPI-818 has the potential to control differentiation of T helper cells and enhance immune responses to tumors. Interference with ITK signaling also can modulate immune responses to various antigens. Optimal doses of CPI-818 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 Th2 related 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 immunologic effects of CPI-818 lead to what is known as Th1 skewing and is made possible by the high selectivity of CPI-818 for ITK. The Company believes the inhibition of specific molecular targets in T cells may be of therapeutic benefit for patients with T cell lymphomas, solid tumors, and in patients with autoimmune and allergic diseases. The Company is conducting a Phase 1/1b trial in patients with refractory T cell lymphomas that was designed to select the optimal dose of CPI-818 and evaluate its safety, PK, target occupancy, immunologic effects, biomarkers and efficacy. Interim data from the Phase 1/1b clinical trial of CPI-818 for T cell lymphoma demonstrated tumor responses in very advanced, refractory, difficult to treat T cell malignancies, and identified a dose that maximally affects T helper cell differentiation.

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 in the tumor microenvironment to the A2A receptor. Adenosine, a metabolite of ATP (adenosine triphosphate), is produced within the tumor microenvironment where it may bind to the adenosine A2A receptor present on immune cells and block their activity.

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 – CPI-818, 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 CPI-818, ciforadenant and mupadolimab; 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 and Angel's Phase 1/1b clinical trial of CPI-818 and the Company's planned meeting with the FDA to discuss a registration clinical trial with CPI-818 for T cell lymphoma later this year; the design of clinical trials, including the target number of patients to be enrolled; the timing of the availability and announcement of clinical data and certain other product development milestones; the estimated amount of net cash used in operating activities for 2023 and its ability to fund operations into 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 Annual Report on Form 10-K for the year ended December 31, 2022, 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 CPI-818, ciforadenant and mupadolimab; the accuracy of the Company's estimates relating to its ability to initiate and/or complete preclinical studies and clinical trials; the results of preclinical studies and interim data from clinical trials not being predictive of future results; 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 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 and year ended December 31, 2022 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 December 31,		Year Ended December 31,	
	2022	2021	2022	2021
	(unaudited)			
Operating expenses:				
Research and development	\$ 4,080	\$ 4,788	\$ 24,468	\$ 29,115
General and administrative	1,586	2,022	8,097	9,515
Total operating expenses	<u>5,666</u>	<u>6,810</u>	<u>32,565</u>	<u>38,630</u>
Loss from operations	(5,666)	(6,810)	(32,565)	(38,630)
Interest income and other expense, net	318	(8)	654	(15)
Gain from sale of property and equipment	22	-	22	-
Sublease income - related party	148	141	587	235
Loss from equity method investment	(4,638)	(2,559)	(10,005)	(4,831)
Net loss	<u>\$ (9,816)</u>	<u>\$ (9,236)</u>	<u>\$ (41,307)</u>	<u>\$ (43,241)</u>
Net loss per share, basic and diluted	<u>\$ (0.21)</u>	<u>\$ (0.20)</u>	<u>\$ (0.89)</u>	<u>\$ (1.03)</u>
Shares used to compute net loss per share, basic and diluted	<u>46,553,511</u>	<u>46,551,954</u>	<u>46,553,511</u>	<u>41,854,110</u>

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

	Year ended December 31,	
	2022	2021
Assets		
Cash, cash equivalents and marketable securities	\$ 42,303	\$ 69,451
Operating lease right-of-use asset	2,217	3,190
Other assets	1,843	2,548
Investment in Angel Pharmaceuticals	21,877	34,266
Total assets	<u>\$ 68,240</u>	<u>\$ 109,455</u>
Liabilities and stockholders' equity		
Accounts payable and accrued liabilities and other liabilities	\$ 9,524	\$ 8,646
Operating lease liability	2,601	3,647
Stockholders' equity	56,115	97,162
Total liabilities and stockholders' equity	<u>\$ 68,240</u>	<u>\$ 109,455</u>

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Photos accompanying this announcement are available at:

<https://www.globenewswire.com/NewsRoom/AttachmentNg/8cad1fa6-2452-4d29-9270-3ea844f7facf>

<https://www.globenewswire.com/NewsRoom/AttachmentNg/9fecd0a2-f763-48d1-b034-c75a997c6396>