# 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): August 8, 2022

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  $\Box$ 

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 August 8, 2022, Corvus Pharmaceuticals, Inc. issued a press release regarding, among other matters, its financial results for the three and six months ended June 30, 2022 and its financial position as of June 30, 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.

<u>Exhibit No.</u>	Description
<u>99.1</u>	Press release of Corvus Pharmaceuticals, Inc. dated August 8, 2022.
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: August 8, 2022

By: <u>/s/ Leiv Lea</u> Leiv Lea Chief Financial Officer

# **Corvus Pharmaceuticals Provides Business Update and Reports Second Quarter 2022 Financial Results**

Prioritizing Development of CPI-818 for T Cell Lymphomas, Autoimmune and Allergic Diseases

Plans to Begin Phase 2 Clinical Trial of Ciforadenant in Front Line Renal Cell Cancer (RCC) in Partnership with Kidney Cancer Consortium in Q3 2022

Pausing Start of Randomized Phase 2 Clinical Trial of Mupadolimab in Lung Cancer; Extends Cash Runway into Early 2024

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

BURLINGAME, Calif., Aug. 08, 2022 (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 second quarter ended June 30, 2022.

"We continue to see encouraging clinical data from the Phase 1 clinical trial of CPI-818 in T cell lymphomas, both in its effects on tumor growth and its effects on normal T cells. Based on this data, along with new preclinical models that demonstrate its potential in autoimmune and allergic diseases, we have decided to focus our efforts on advancing the development of CPI-818," said Richard A. Miller, M.D., co-founder, president and chief executive officer of Corvus. "The intensification of efforts on this program brings other advantages – we expect that we can generate additional clinical data in the near-term, we believe CPI-818 is the most advanced program targeting ITK inhibition and our team has expertise developing and launching an analogous target in BTK inhibition with Ibrutinib."

"We will continue to advance ciforadenant, our adenosine 2a inhibitor, which also has the potential to deliver near-term clinical data from our planned Phase 2 clinical trial. We remain excited about mupadolimab, our B cell activating anti-CD73 antibody, which will now be paused in development but remains ready to enter a randomized Phase 2 clinical trial in front line lung cancer. Altogether, our portfolio prioritization extends our cash runway and gives us the potential to deliver near-term clinical data for CPI-818, which is uniquely positioned to address a broad range of indications in cancer, autoimmunity and allergy."

#### **Business Update and Strategy**

#### **CPI-818 (selective ITK inhibitor)**

Corvus and its partner in China, Angel Pharmaceuticals, are enrolling patients with relapsed T cell lymphomas (TCL) in Phase 1/1b trial evaluating single agent therapy with CPI-818. Angel Pharmaceuticals is responsible for all expenses related to conducting the clinical trial in China.

- Monitoring of immune modulation of normal T cells as well as safety and anti-tumor activity are being assessed in the clinical trial, with additional data from the trial expected later this year.
- As recently reported, the Company has identified 200 mg orally twice per day as the optimum dosing regimen for CPI-818. This dose regimen has been shown to affect T cell differentiation and induce the generation of Th1 helper cells while blocking the development of Th2 cells. Corvus and Angel are now enrolling additional patients with TCL in a 200 mg cohort of the clinical trial.
- As of July 22, 2022 in the 200 mg cohort, 12 patients have been enrolled and 8 are evaluable for response. There has been 1 complete response (CR) lasting 25 months; 1 nodal CR lasting 16 months; 1 partial response (PR) ongoing at 2 months follow up. Five patients had stable disease (SD), 2 of the patients with SD have been on treatment for approximately 12 weeks and continue on study. Two additional patients are on treatment and have not yet had their disease monitoring assessments. An additional patient in the 600 mg cohort also had a PR.
- As of July 22, 2022, analysis of blood in 4 of 4 patents treated in the 200 mg cohort showed increases in Th1 cells compared to baseline and increases in terminally differentiated T effector memory cells; these are T cells that are antigen primed and capable of destroying tumor cells. Tumor biopsy from 1 patient taken during response demonstrated an increase in these cells in the tumor.
- Three of three patients in the 200 mg cohort with high baseline, pretreatment eosinophil counts demonstrated reductions in circulating eosinophils during treatment with CPI-818. Eosinophils are white blood cells that play a key role in allergic and autoimmune diseases and they are often elevated in patients with TCL.
- As of July 22, 2022, no dose limiting toxicities (DLTs) have been observed at doses up to 600 mg orally twice per day.

Corvus is also developing CPI-818 for autoimmune and allergic diseases and is preparing to initiate clinical trials for certain autoimmune diseases.

- CPI-818 has demonstrated activity in various animal models of autoimmunity including models of systemic lupus erythematosus, psoriasis, inflammatory bowel disease and graft versus host disease. Some of this research was presented at the annual meetings of the American Society of Hematology in 2020 and 2021.
- In July, the Company appointed James Rosenbaum, M.D. as Senior Vice President, Research, with an initial focus on leading the Company's development efforts for CPI-818 in autoimmune and allergic diseases. Dr. Rosenbaum previously served as Professor of Inflammatory Diseases and Chair, Division of Arthritis & Rheumatic Diseases, at Oregon Health & Science University and has authored over 600 publications.

## Ciforadenant (adenosine 2a receptor antagonist)

- The Company plans to collaborate with the Kidney Cancer Clinical Trials Consortium to initiate an open-label Phase 2 clinical trial evaluating ciforadenant as a first-line therapy for metastatic RCC in combination with ipilimumab (anti-CTLA-4) and nivolumab (anti-PD-1). The clinical trial, which is anticipated to be initiated in the third quarter 2022, will enroll up to 60 patients and is intended to evaluate the potential for ciforadenant to generate increased complete responses and deep responses in the front-line setting.
- The Kidney Cancer Clinical Trials Consortium is comprised of a group of leading cancer centers in the United States led by investigators at MD Anderson. The trial design is based on Corvus' preclinical research published in 2018 in Cancer Immunology Research that demonstrated impressive antitumor control and cures in several animal models using ciforadenant in combination with anti-CTLA4 and anti-PD1.

# Mupadolimab (anti-CD73)

- The Company has completed enrollment in its two Phase 1/1b clinical trial expansion cohorts of patients with (1) head and neck cancers that have failed previous treatment with anti-PD-1 therapy and chemotherapy and (2) relapsed refractory NSCLC who have failed previous treatment with anti-PD(L)-1 therapy and chemotherapy.
- Based on the results to-date, the Company believes this program is ready to advance into a randomized Phase 2 clinical trial evaluating mupadolimab in combination with pembrolizumab and chemotherapy as a front-line therapy for the treatment of patients with NSCLC. However, the Company is delaying the initiation of this clinical trial in order to prioritize the development of CPI-818 and to conserve capital.
- Angel Pharmaceuticals plans to continue the development of mupadolimab in China. The CDE (Center for Drug Evaluation) in China has accepted for filing the IND to initiate a Phase 1 trial with mupadolimab alone and together with pembrolizumab in patients with advanced NSCLC and head and neck cancer.

## **Financial Results**

As of June 30, 2022, Corvus had cash, cash equivalents and marketable securities totaling \$56.7 million. This compared to cash, cash equivalents and marketable securities of \$69.5 million as of December 31, 2021. Corvus expects full year 2022 net cash used in operating activities to be between \$27 million and \$29 million, resulting in a projected cash balance of between \$40.5 million and \$42.5 million as of December 31, 2022. Based on its current plans, the Company expects its cash to fund operations into early 2024.

Research and development expenses for the three months ended June 30, 2022 totaled \$4.9 million compared to \$9.1 million for the same period in 2021. The decrease of \$4.2 million was primarily due to reduced clinical trial costs associated with the mupadolimab Phase 3 trial in COVID-19 patients.

The net loss for the three months ended June 30, 2022 was \$8.4 million compared to a net loss of \$11.8 million for the same period in 2021. Total stock compensation expense for the three months ended June 30, 2022 was \$0.7 million compared to \$1.2 million for the same period in 2021 and the non-cash loss from the Company's equity method investment in Angel Pharmaceuticals was \$1.6 million for the three months ended June 30, 2022 compared to \$0.5 million in the same period in 2021.

# **Conference Call Details**

Corvus will host a conference call and webcast today, Monday, August 8, 2022, at 4:30 p.m. ET (1:30 p.m. PT), during which time management will provide a business update and discuss the second quarter 2022 financial results. The conference call can be accessed by dialing 1-844-825-9789 (toll-free domestic) or 1-412-317-5180 (international) and using the conference ID 10169996. 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. 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 Th2 cells. Th1 T cells are required for immunity to tumors, viral infections and other infectious diseases. Th2 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 the drug 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 and leukemias 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 Pharmaceuticals 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, mupadolimab and ciforadenant; the Company's ability and Angel Pharmaceutical's 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 trials of CPI-818 as well as the Company's plan to initiate a Phase 2 clinical trial with ciforadenant in collaboration with the Kidney Cancer Clinical Trials Consortium; the timing of the availability and announcement of clinical data and certain other product development milestones, including the timing of initial results in the Phase 1/1b clinical trial for CPI-818; the expected trial design and number of patients enrolled in the Company's upcoming planned clinical trials, and the estimated amount of net cash used in operating activities for 2022 and adequacy of cash on hand. 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 quarter ended June 30, 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 may not be predictive of future results; the unpredictability of the regulatory process; regulatory developments in the United States, and other foreign countries; 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 2022 and cash on hand providing funding into early 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 June 30, 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)

	June 30,			June 30,				
	2022 2021		2022		2021			
		(unaudited)			(unaudited)			
Operating expenses:								
Research and development	\$	4,923	\$	9,106	\$	10,023	\$	17,336
General and administrative		2,090		2,184		4,403		5,437
Total operating expenses		7,013		11,290		14,426		22,773
Loss from operations		(7,013)		(11,290)		(14,426)		(22,773)
Interest income and other expense, net		100		1		111		4
Sublease income - related party		146				292		
Loss from equity method investment		(1,596)		(463)		(2,637)		(563)
Net loss	\$	(8,363)	\$	(11,752)	\$	(16,660)	\$	(23,332)
Net loss per share, basic and diluted	\$	(0.18)	\$	(0.28)	\$	(0.36)	\$	(0.61)
Shares used to compute net loss per share, basic and diluted	4	46,553,511		42,247,094		46,553,511		38,402,464
			-		-			

# CORVUS PHARMACEUTICALS, INC. CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands)

	June 30, 2022		December 31, 2021	
	(ur	naudited)		
Assets				
Cash, cash equivalents and marketable securities	\$	56,723	\$	69,451
Operating lease right-of-use asset		2,712		3,190
Other assets		2,925		2,548
Investment in Angel Pharmaceuticals		30,181		34,266
Total assets	\$	92,541	\$	109,455
Liabilities and stockholders' equity				
Accounts payable and accrued liabilities and other liabilities	\$	9,021	\$	8,646
Operating lease liability		3,134		3,647
Stockholders' equity		80,386		97,162
Total liabilities and stockholders' equity	\$	92,541	\$	109,455

# **INVESTOR CONTACT:**

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

# **MEDIA CONTACT:**

Aulani Capuchin Real Chemistry +1-559-355-2673 acapuchin@realchemistry.com