

**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, 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 August 8, 2023, Corvus Pharmaceuticals, Inc. issued a press release regarding, among other matters, its financial results for the three and six months ended June 30, 2023 and its financial position as of June 30, 2023, 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 August 8, 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: August 8, 2023

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

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

Interim Phase 1/1b clinical results with soquelitinib and published clinical studies on mechanism of action continue to support potential of ITK inhibition as novel immunotherapy for hematologic and solid tumors

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

BURLINGAME, Calif., Aug. 08, 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 second quarter ended June 30, 2023.

“During the second quarter, we continued to strengthen the scientific and clinical foundation for the potential use of soquelitinib for a variety of cancers and have several important near-term milestones for our clinical programs,” said Richard A. Miller, M.D., co-founder, president and chief executive officer of Corvus. “We believe that soquelitinib, our selective ITK inhibitor, may offer a new approach to cancer immunotherapy based on its unique mechanism of action, which is to increase infiltration of cytotoxic T cells into tumors, increase the cytolytic capacity of T cells and reduce T cell exhaustion. This mechanism is distinct and independent from current immuno-oncology therapies based on checkpoint inhibition. We remain on track to meet with the FDA this quarter to discuss a potential registrational Phase 3 clinical trial with soquelitinib in relapsed T cell lymphomas (TCL). We also are planning to initiate clinical studies with soquelitinib in solid tumors. Lastly, enrollment is ongoing in clinical trials evaluating our partner led programs, ciforadenant and mupadolimab, with the potential for initial ciforadenant data from the Phase 1b/2 trial in front line therapy for patients with metastatic renal cell cancer to be released by year end.”

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 TCL in a Phase 1/1b clinical trial evaluating single agent therapy with soquelitinib, including utilizing its recently incorporated biomarker based on absolute lymphocyte count (ALC). 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, a total of 30 patients were enrolled at the optimum 200 mg two-times a day dose, including 20 evaluable for tumor response. There were 3 complete responses (CR) and 3 partial responses (PR) with one of these PRs demonstrating continued regression of the tumor. One of the patients with a CR and two with PRs remained on therapy. A total of ten patients remained on therapy, including six who have not had their initial tumor response evaluation. For patients with ALC above 900 per cubic milliliter of blood, objective responses (CR plus PR) were seen in 6 of 14 patients with disease control (CR, PR and stable disease) in 12 of 14 patients. No objective responses were seen in six patients (0 for 6) with ALC below 900.
- Based on the current enrollment rate of the Phase 1/1b clinical trial, Corvus 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 potential registrational Phase 3 randomized clinical trial. As recommended by the FDA, Corvus plans to meet with the FDA to discuss such a clinical trial; it is anticipated that this meeting will take place during the third quarter of this year.

Soquelitinib Preclinical Data in Hematologic and Solid Tumors

- On July 6, 2023, Corvus announced the publication of preclinical data on soquelitinib as a preprint at bioRxiv, which highlighted the selective inhibition of ITK to potentially enhance anti-tumor immune response to hematologic and solid tumors and provide a novel approach to cancer immunotherapy. Important findings from the preclinical studies include the demonstration of soquelitinib’s ability to induce skewing and enrichment of T-helper type 1 (Th1) cells and increase infiltration of cancer killing T cells into tumors with greater potency and less resistance due to exhaustion. Data also showed that soquelitinib monotherapy led to *in vivo* anti-tumor activity in several mouse tumor models, including colon, renal, melanoma, B cell and T cell tumors.

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 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 before the end of 2023.

Support for the mechanism of action and anti-tumor activity of ciforadenant was recently presented at the Japanese Cancer Association and American Association for Cancer Research (JCA-AACR) Precision Cancer Medicine International Conference, which took place June 28-30, 2023 in Kyoto, Japan. The presentation highlighted preclinical data suggesting a synergy between ciforadenant and immune checkpoint blockade (ICB), leading to a proinflammatory response.

- 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 June 30, 2023, Corvus had cash, cash equivalents and marketable securities of \$37.0 million as compared to \$42.3 million as of December 31, 2022. During the quarter ending June 30, 2023, the Company sold 2,329,851 shares of its common stock through its at-the-market (ATM) program, generating net proceeds to the Company of \$7.5 million. Corvus expects full year 2023 net cash used in operating activities to be between approximately \$20 million and \$22 million, resulting in a projected cash balance of between \$28 million and \$30 million as of December 31, 2023. Based on its current plans, Corvus expects its cash to fund operations into the second half of 2024.

Research and development expenses for the three months ended June 30, 2023 totaled \$4.0 million compared to \$4.9 million for the same period in 2022. The decrease of \$0.9 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 June 30, 2023 was \$6.5 million compared to a net loss of \$8.4 million for the same period in 2022. Total stock compensation expense for the three months ended June 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 \$1.3 million for the three months ended June 30, 2023 compared to \$1.6 million in the same period in 2022.

Conference Call Details

Corvus will host a conference call and webcast today, Tuesday, August 8, 2023, 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 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 and is in a mid-stage clinical trial for patients with 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 that has selectively inhibited ITK (interleukin-2-inducible T cell kinase) in preclinical studies. ITK, an enzyme, 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. Recent clinical data in T cell lymphomas, and preclinical studies in murine solid tumor models, suggests that soquelitinib 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. 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 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 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. 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 soquelitinib and evaluate its safety, PK, target occupancy, immunologic effects, biomarkers and efficacy. Interim data from the Phase 1/1b clinical trial of soquelitinib for T cell lymphoma demonstrated tumor responses in very advanced, refractory, difficult to treat T cell malignancies, and identified a dose that maximally drives Th1 skewing.

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 1/1b clinical trial of ciforadenant; the timing of the Company's planned meeting with the FDA to discuss a registration clinical trial with soquelitinib for TCL during the third quarter of this year; the timing of initial data from the Phase 1b/2 clinical trial with ciforadenant; the estimated amount of net cash used in operating activities for 2023 and its ability to fund operations into the second half of 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 June 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 the second half of 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, 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		Six Months Ended	
	June 30,		June 30,	
	2023	2022	2023	2022
	(unaudited)		(unaudited)	
Operating expenses:				
Research and development	\$ 3,968	\$ 4,923	\$ 8,562	\$ 10,023
General and administrative	1,654	2,090	3,634	4,403
Total operating expenses	<u>5,622</u>	<u>7,013</u>	<u>12,196</u>	<u>14,426</u>
Loss from operations	(5,622)	(7,013)	(12,196)	(14,426)
Interest income and other expense, net	403	100	779	111
Sublease income - related party	—	146	56	292
Loss from equity method investment	(1,284)	(1,596)	(3,015)	(2,637)
Net loss	<u>\$ (6,503)</u>	<u>\$ (8,363)</u>	<u>\$ (14,376)</u>	<u>\$ (16,660)</u>
Net loss per share, basic and diluted	<u>\$ (0.14)</u>	<u>\$ (0.18)</u>	<u>\$ (0.31)</u>	<u>\$ (0.36)</u>
Shares used to compute net loss per share, basic and diluted	<u>47,497,414</u>	<u>46,553,511</u>	<u>47,029,396</u>	<u>46,553,511</u>

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

	<u>June 30,</u> <u>2023</u>	<u>December 31,</u> <u>2022</u>
	(unaudited)	
Assets		
Cash, cash equivalents and marketable securities	\$ 37,017	\$ 42,303
Operating lease right-of-use asset	1,691	2,217
Other assets	1,316	1,843
Investment in Angel Pharmaceuticals	18,017	21,877
Total assets	<u>\$ 58,041</u>	<u>\$ 68,240</u>
Liabilities and stockholders' equity		
Accounts payable and accrued liabilities and other liabilities	\$ 6,559	\$ 9,524
Operating lease liability	1,999	2,601
Stockholders' equity	49,483	56,115
Total liabilities and stockholders' equity	<u>\$ 58,041</u>	<u>\$ 68,240</u>

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