

**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 6, 2024

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
(Address of principal executive offices)

94010
(Zip Code)

(Registrant's telephone number, including area code): (650) 900-4520

Former name or former address, if changed since last report: Not applicable

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, Par Value \$0.0001 per share	CRVS	Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§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 6, 2024, Corvus Pharmaceuticals, Inc. issued a press release regarding, among other matters, its financial results for the three and six months ended June 30, 2024 and its financial position as of June 30, 2024, 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 6, 2024.
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 6, 2024

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

Corvus Pharmaceuticals Provides Business Update and Reports Second Quarter 2024 Financial Results

Early Results from Soquelitinib Phase 1 Randomized Trial in Atopic Dermatitis Demonstrate Clinical Activity and Corresponding Changes in Cytokine Levels Consistent with ITK Inhibition Mechanism of Action

Soquelitinib Registration Phase 3 Trial in Peripheral T Cell Lymphoma (PTCL) Advancing Toward Initial Enrollment in Q3 2024; New Complete Response Achieved in Ongoing Phase 1/1b Clinical Trial

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

BURLINGAME, Calif., Aug. 06, 2024 (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, 2024.

“We have seen growing evidence supporting the central role of ITK in T cell biology and the significant potential of ITK inhibition as a new mechanism to treat a broad range of immune diseases and cancers,” said Richard A. Miller, M.D., co-founder, president and chief executive officer of Corvus. “This includes early data from our Phase 1 clinical trial of soquelitinib in atopic dermatitis and our ongoing preclinical work exploring ITK inhibition in autoimmunity and inflammation. Based on this, we are increasingly optimistic that our ITK platform has the potential to improve clinical outcomes for a range of indications as an oral medication with an attractive tolerability profile. We have leveraged our experience in T cell lymphomas which has allowed us to gain a deeper understanding of the role of ITK in T cell biology that we can now apply to immune diseases. We remain on track to initiate a Phase 3 registrational trial in PTCL in the third quarter.”

Business Update and Strategy

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

Soquelitinib for Immune Diseases

- Corvus continues to enroll patients at multiple clinical sites in its randomized, placebo-controlled Phase 1 clinical trial of soquelitinib in patients with moderate to severe atopic dermatitis. The trial is planned to enroll 64 patients that have failed at least one prior therapy across four different 28-day dosing regimens of soquelitinib compared to a placebo group. The endpoints include safety and improvement in Eczema Area and Severity Index. Patients and physicians will be blinded to treatment assignment.
 - Initial results, as of July 31, 2024, from three evaluable patients in the first cohort of the trial that completed the 28-day dosing regimen and follow-up visit demonstrated signs of clinical activity and corresponding changes in serum cytokine levels that are consistent with soquelitinib’s mechanism of action. These patients received a dose of 100 mg two-times a day, the lowest dose level planned for the study.
 - Corvus anticipates interim data from the Phase 1 clinical trial will be presented in the fourth quarter of 2024.
- Recent published data from researchers at Cornell University demonstrated that ITK controls the fate of inflammatory Th17 cells. When ITK is inhibited by soquelitinib, the Th17 cells convert or switch to Treg cells that suppress inflammation. Soquelitinib treatment in an asthma model of mice with allergic airway inflammation significantly reduced the percentage of Th17 cells in the lung resulting in an increase in the ratio of Treg to Th17 cells. These studies confirm our understanding of the role of specific ITK inhibition in inflammation and are relevant to many immune diseases.
- Corvus continues to advance its next-generation ITK inhibitor preclinical product candidates, which were designed to deliver precise T-cell modulation that is optimized for specific immunology indications. The next-generation ITK inhibitor candidates are part of the Company’s ongoing business development efforts to maximize the potential of the Company’s ITK inhibitor programs in immune diseases and cancers.

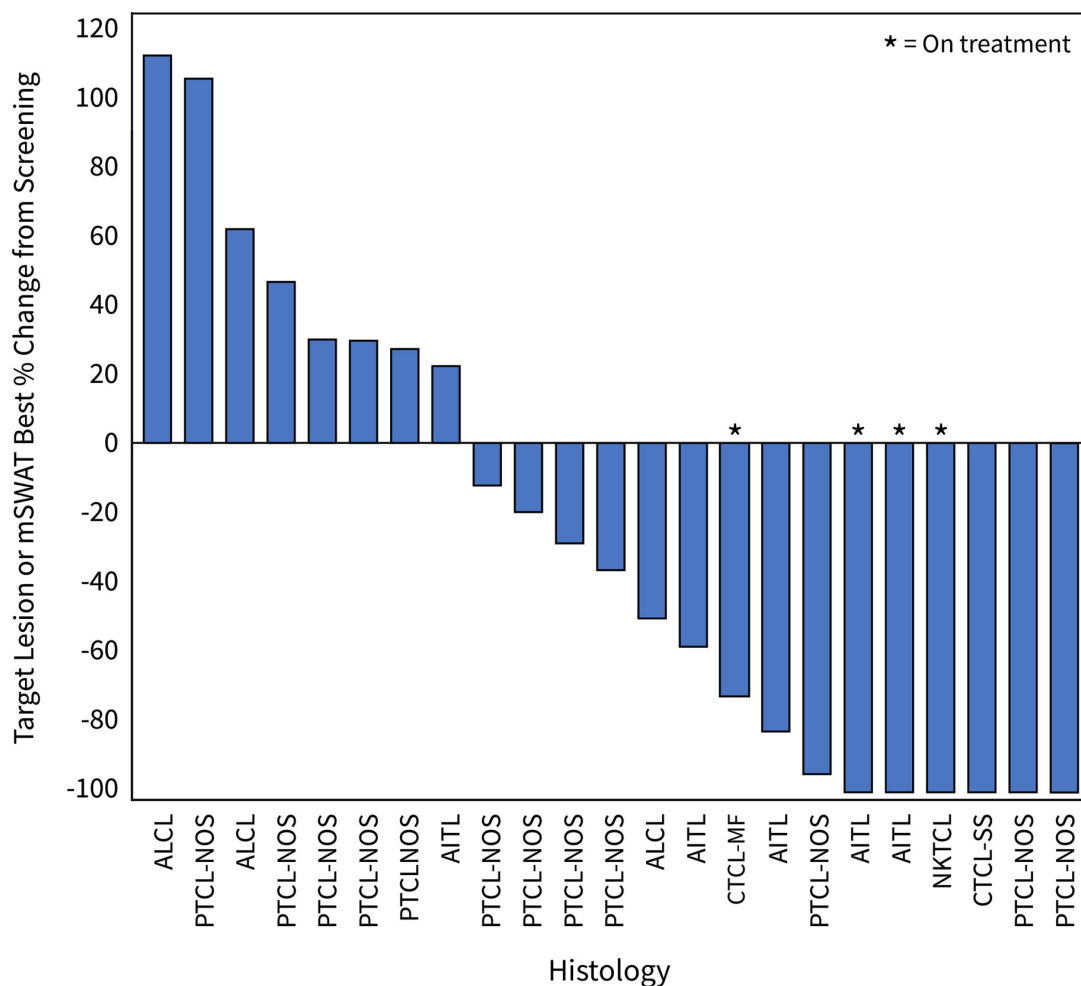
Soquelitinib for T Cell Lymphoma

- Corvus continues to follow patients with relapsed T cell lymphoma in its Phase 1/1b clinical trial (no longer enrolling new patients) evaluating single agent therapy with soquelitinib. Updated interim data as of July 16, 2024:
 - A total of 25 patients were enrolled in the Phase 1/1b trial at the optimum 200 mg two-times a day dose and meet the eligibility criteria for the planned registrational Phase 3 clinical trial based on ≥ 1 and ≤ 3 prior therapies, including 23 evaluable patients.
 - For the 23 evaluable patients, objective responses (complete response, CR plus partial response, PR) were seen in nine patients (39%), including six CRs (26%) and three PRs. Compared to the prior data reported as of May 3, 2024, one patient with continued tumor regression achieved a CR that previously had a PR at the first follow up visit. See waterfall plot below.
 - Disease control (CR, PR and stable disease) was seen in 14 of 23 patients (61%). The stable disease group included five patients who achieved tumor reductions that did not meet the criteria for a PR.
- Corvus anticipates initiating a registrational Phase 3 clinical trial of soquelitinib in patients with relapsed PTCL in the third quarter of 2024. There are currently no FDA fully approved agents for the treatment of relapsed PTCL and the FDA has granted Orphan Drug Designation for soquelitinib for the treatment of T cell lymphoma. Recently, the Company received a

Pediatric Waiver from the FDA indicating that it would not be required to conduct clinical trials in a pediatric population for this indication.

- As recently announced, soquelitinib has received Fast Track designation for treatment of adult patients with relapsed or refractory peripheral T cell lymphoma after at least 2 lines of systemic therapy.

Waterfall Plot for Patients in the 200 mg Dose Cohort of the Soquelitinib Phase 1/1b Clinical Trial for Peripheral T Cell Lymphoma. The plot shows the best percent change in tumor volume in the 23 evaluable patients (eligible patient population), as of July 16, 2024, that were measurable by CT scan or by Modified Severity-Weighted Assessment Tool (mSWAT) for patients with cutaneous involvement. PTCL-NOS, peripheral T cell lymphoma not otherwise specified; CTCL, cutaneous T cell lymphoma of either Sezary or mycosis fungoides type; NKTCL, natural killer cell T cell lymphoma; ALCL, anaplastic large cell lymphoma; AITL, angioimmunoblastic T cell lymphoma.



Collaboration with Kidney Cancer Research Consortium: Ciforadenant (adenosine A2a receptor inhibitor)

- Corvus is collaborating with the Kidney Cancer Research Consortium in 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 efficacy endpoint for the trial is deep response rate, defined as CR plus PRs of greater than 50% tumor volume reduction. The clinical trial is expected to enroll up to 60 patients and as of May 31, 2024 a total of 32 patients were enrolled in the trial. The protocol defined, interim pre-specified statistical threshold for efficacy is a 50% increase above the 32% deep response rate seen with previous ipilimumab/nivolumab combination trials in RCC conducted by investigators at the Kidney Cancer Research Consortium. As of May 31, 2024, the interim analysis of the clinical trial has met the threshold for efficacy and therefore enrollment continues.
- In July 2024, a new U.S. patent was issued (*United States Patent No. 12,023,337*) by the U.S. Patent and Trademark Office that covers the use of ciforadenant for the treatment of cancer; foreign counterparts are pending.

Partner Led Program: Mupadolimab (anti-CD73)

- Angel Pharmaceuticals, Corvus’ partner in China, is enrolling patients in an expansion cohort of a Phase 1/1b clinical trial of mupadolimab in patients with relapsed non-small cell lung cancer (NSCLC). In this clinical trial, patients will receive mupadolimab monotherapy.

Financial Results

As of June 30, 2024, Corvus had cash, cash equivalents and marketable securities of \$47.2 million as compared to \$27.1 million as of December 31, 2023. During the quarter ended June 30, 2024, the Company completed a registered direct offering in which it sold shares of common stock, pre-funded warrants and common warrants, generating \$30.3 million in net proceeds.

Corvus expects full year 2024 net cash used in operating activities to be between approximately \$24 million and \$27 million, resulting in a projected cash balance of between approximately \$31 million and \$34 million at December 31, 2024. Based on its current plans, Corvus expects its cash to fund operations into the fourth quarter of 2025.

Research and development expenses for the three months ended June 30, 2024 totaled \$4.1 million compared to \$4.0 million for the same period in 2023. The increase of \$0.1 million was primarily due to higher clinical trial costs associated with the development of soquelitinib.

The net loss for the three months ended June 30, 2024 was \$4.3 million compared to a net loss of \$6.5 million for the same period in 2023. Total stock compensation expense for the three months ended June 30, 2024 was \$0.8 million compared to \$0.5 for the same period in 2023 and the non-cash loss from Corvus' equity method investment in Angel Pharmaceuticals was \$0.6 million for the three months ended June 30, 2024 compared to a loss of \$1.3 million for the same period in 2023. In addition, the Company recorded a non-cash gain of \$1.8 million from the change in fair value of its warrant liability during the three months ended June 30, 2024 due to the warrants issued in the registered direct offering.

Conference Call Details

Corvus will host a conference call and webcast today, Tuesday, August 6, 2024, 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 2024 financial results. The conference call can be accessed by dialing 1- 800-717-1738 (toll-free domestic) or 1- 646-307-1865 (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. Its other clinical-stage candidates are being developed for a variety of cancer indications. For more information, visit www.corvuspharma.com.

About Soquelitinib

Soquelitinib (formerly CPI-818) is an investigational small molecule drug given orally designed to selectively inhibit ITK (interleukin-2-inducible T cell kinase), an enzyme that is expressed predominantly in T cells and plays a role in T cell and natural killer (NK) cell immune function. 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 PTCL. Soquelitinib also is now being investigated in a randomized placebo controlled phase 1 clinical trial in patients with atopic dermatitis. The immunologic effects of soquelitinib lead to what is known as Th1 skewing and inhibition of Th2 and Th17 cells. 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. Soquelitinib has been shown to affect T cell differentiation and induce the generation of Th1 helper cells while blocking the development of both Th2 and Th17 cells and production of their secreted cytokines. Th1 T cells are required for immunity to tumors, viral infections and other infectious diseases. Th2 and Th17 helper T cells are involved in the pathogenesis of many autoimmune and allergic diseases. The Company believes the inhibition of specific molecular targets in T cells may be of therapeutic benefit for patients with cancers, including solid tumors, and in patients with autoimmune and allergic diseases.

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 Atopic Dermatitis

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

that result in inflammation. Soquelitinib has been shown in preclinical studies to inhibit cytokine production from Th2 lymphocytes.

About 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 hematological cancers and autoimmune diseases; 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 clinical trial for atopic dermatitis with soquelitinib; the timing of and the Company's ability to launch clinical trials, including the soquelitinib registrational Phase 3 clinical trial for PTCL; the design of clinical trials, including the timeline for initiation, target or expected number of patients to be enrolled, expected number of sites and certain other product development milestones, including in regards to the Phase 1 clinical trial for atopic dermatitis with soquelitinib; the availability and timing of clinical and preclinical data announcements and clinical readouts, including early data from the Phase 1 clinical trial for atopic dermatitis with soquelitinib and preclinical data supporting the broad potential of ITK inhibition in immune and inflammatory disease; the estimated amount of net cash used in operating activities for 2024 and its ability to fund operations into the fourth quarter of 2025. 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, 2024, 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 2024 and cash on hand providing funding into the fourth quarter of 2025 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, 2024 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 June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
	(unaudited)		(unaudited)	
Operating expenses:				
Research and development	\$ 4,114	\$ 3,968	\$ 8,189	\$ 8,562
General and administrative	1,821	1,654	3,999	3,634
Total operating expenses	<u>5,935</u>	<u>5,622</u>	<u>12,188</u>	<u>12,196</u>
Loss from operations	(5,935)	(5,622)	(12,188)	(12,196)
Interest income and other expense, net	434	403	750	779
Change in fair value of warrant liability	1,816	—	1,816	—
Sublease income - related party	—	—	—	56
Loss from equity method investment	(577)	(1,284)	(341)	(3,015)
Net loss	<u>\$ (4,262)</u>	<u>\$ (6,503)</u>	<u>\$ (9,963)</u>	<u>\$ (14,376)</u>
Net loss per share, basic and diluted	<u>\$ (0.07)</u>	<u>\$ (0.14)</u>	<u>\$ (0.18)</u>	<u>\$ (0.31)</u>
Shares used to compute net loss per share, basic and diluted	<u>59,710,265</u>	<u>47,497,414</u>	<u>54,374,423</u>	<u>47,029,396</u>

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

	June 30,	December 31,
	2024	2023
	(unaudited)	
Assets		
Cash, cash equivalents and marketable securities	\$ 47,246	\$ 27,149
Operating lease right-of-use asset	578	1,149
Other assets	1,333	1,132
Investment in Angel Pharmaceuticals	15,404	16,123
Total assets	<u>\$ 64,561</u>	<u>\$ 45,553</u>
Liabilities and stockholders' equity		
Accounts payable and accrued liabilities and other liabilities	\$ 5,517	\$ 5,495
Operating lease liability	700	1,374
Warrant liability	7,118	—
Stockholders' equity	51,226	38,684
Total liabilities and stockholders' equity	<u>\$ 64,561</u>	<u>\$ 45,553</u>

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A photo accompanying this announcement is available at <https://www.globenewswire.com/NewsRoom/AttachmentNg/a451d560-a41c-4487-99ca-cd7de11e4274>