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): February 4, 2021

CORVUS PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-37719**	**46-4670809**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification Number)**

863 Mitten Road, Suite 102
Burlingame, CA 94010
(Address of principal executive offices, including Zip Code)

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

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 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2). 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 8.01 Other Events.

On February 4, 2021, Corvus Pharmaceuticals, Inc. ("Corvus" or the "Company") announced that that it has initiated a Phase 3 clinical trial of CPI-006 for the treatment of hospitalized patients with COVID-19. The study is expected to enroll approximately 1,000 patients at sites in North America, Europe, South Africa and Latin America.

CPI-006 is a humanized monoclonal antibody that is designed to bind to and activate B cells that Corvus believes has the potential to provide a unique immunotherapy approach for the treatment of infectious diseases, including COVID-19. In a Phase 1 study involving 28 hospitalized, high-risk patients with moderate COVID-19 treated with CPI-006, no patients progressed to requiring mechanical ventilation and the median time to discharge from the hospital was 3.5 days. This compares favorably to published reports showing that, on average, approximately 20% of similarly affected patients will progress to requiring invasive mechanical ventilation. Patients in the study generated high titers of polyclonal antibodies against a diverse range of targets on the SARS-CoV-2 virus that were sustained over several months. They also had increased levels of circulating memory B cells, which could lead to long-term immunity.

Serum from 2 of 2 patients treated with CPI-006 early in the pandemic (July 2020), and before variants were discovered, were tested in neutralization assays against both the UK variant and wild type receptor binding domain of SARS-CoV-2 (N501Y mutation). Day 28 post CPI-006 treatment serum showed increases in neutralization titers of 4.5 fold and 1.7 fold to the UK variant for the two patients respectively, compared to the wild type virus. These data will require further confirmation with many more additional patients, but suggest that CPI-006 elicited a broad anti-viral response that may address the problem of immune escape.

The Phase 3 double-blind study, which was designed with guidance from the Food and Drug Administration (FDA), will evaluate the efficacy and safety of CPI-006 compared to placebo in hospitalized patients with mild-to-moderate COVID-19. Patients will be randomized in a 1:1:1 ratio to receive a single intravenous CPI-006 dose of either 2.0 mg/kg or 1.0 mg/kg or placebo; all patients will receive standard of care treatments for COVID-19. The primary endpoint is the proportion of patients progressing to respiratory failure or death during the 28 days after dosing. Respiratory failure is defined as requiring non-invasive or invasive mechanical ventilation. Additional secondary endpoints include time to recovery, time to resolution of COVID-19 symptoms, anti-viral antibody responses, etc. An interim futility and efficacy analysis will be conducted by an independent data monitoring committee when approximately 60% of subjects complete the 28-day post-treatment visit. Results from the study are expected to be available in the fourth quarter 2021.

Corvus also announced that in collaboration with its Chinese partner, Angel Pharmaceuticals, it plans to initiate a global Phase 2 trial with CPI-818, an ITK inhibitor, in refractory peripheral T cell lymphoma by the end of 2021. The Company also announced its plans to collaborate with an academic consortium to evaluate ciforadenant, its A2A receptor antagonist, for the first line treatment of metastatic renal cell carcinoma in combination with pembrolizumab and a tyrosine kinase inhibitor.

Forward-Looking Statements

To the extent that statements contained herein are not descriptions of historical facts regarding Corvus, they are forward-looking statements, including statements related to the potential safety and efficacy of CPI-006, CPI-818 and ciforadenant, the Company's ability to develop and advance product candidates into and successfully complete preclinical studies and clinical trials, including the Company's Phase 3 clinical trial of CPI-006 for COVID-19, the timing of the availability and announcement of clinical data and certain other product development milestones, and the sufficiency of the Company's cash resources. All statements other than statements of historical fact contained in this Current Report on Form 8-K 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 September 30, 2020, filed with the Securities and Exchange Commission on October 29, 2020, 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-006, CPI-818 and ciforadenant; 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; whether the FDA accepts data from trials conducted in foreign locations, including China; the unpredictability of any ongoing or future trade dispute between the United States and China; the costs of clinical trials may exceed expectations; the Company's ability to raise additional capital; the effects of COVID-19 on the Company's clinical programs and business operations.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

CORVUS PHARMACEUTICALS, INC.

Date: February 4, 2021

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