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): September 10, 2020

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 September 10, 2020, Corvus Pharmaceuticals, Inc. ("Corvus" or the "Company") announced updated data from its ongoing Phase 1 clinical trial investigating the potential for CPI-006 to provide a novel immunotherapy approach for patients with COVID-19. The results demonstrated that all evaluable patients treated in the first two cohorts (0.3 and 1.0 mg dose of CPI-006) of the study produced significant titers of antibody to SARS-CoV-2 within seven days of receiving the treatment, with levels of antibody, including neutralizing antibodies, continually increasing out to 28 days. In addition, all of the patients in the first two cohorts were discharged from the hospital with clinical improvement and none experienced any drug-related safety issues.

The open-label, Phase 1 clinical trial is expected to enroll up to 30 hospitalized COVID-19 patients with mild to moderate symptoms. Pursuant to the study, patients will receive a single dose of CPI-006, with levels of 0.3, 1.0, 3.0 and 5.0 mg/kg, escalating in four cohorts as the study progresses. Patients will receive medications, therapies, and interventions per standard treatment protocols for COVID-19 for the duration of the study. The primary efficacy endpoint is the change in serum immunoglobulin (IgM and IgG) anti-SARS-CoV-2 levels compared to baseline at day 28. The study also will examine safety and other clinical endpoints, including time to resolution of symptoms and duration of hospitalization. The study has also completed enrollment in the third cohort (3.0 mg dose of CPI-006) of five patients.

In the study, the median age of the patients was 64 years (range 28-76 years) and all the patients had comorbidities that increased their COVID-19 risk: diabetes (4), hypertension (2), obesity (7), and/or cancer (2). The median duration of symptoms prior to treatment with CPI-006 was 8 days (range 1-21 days). The key highlights from these 10 patients, include:

- Nine of nine patients with pre-treatment serum samples available had low pre-treatment levels of anti-SARS-CoV-2 antibodies independent of the duration of their prior COVID-19 symptoms.

- IgG and IgM antibody titers against the SARS-CoV-2 trimeric spike and/or receptor binding domain (RBD) increased in eight of eight evaluable patients within seven days of a single infusion of low doses of CPI-006. One patient did not have a pre-treatment serum sample available but had a sample collected one day after receiving CPI-006 and this sample exhibited a high titer, which continued to increase. In five patients measured, the antibodies were neutralizing; one patient with lymphopenia showed a delay in generating neutralizing antibodies.

- In all patients evaluated, the antibody responses continued to increase out to 28 days post treatment with CPI-006. Rising titers of >1:200,000 to spike protein and >1:100,000 to RBD were observed. IgM titers also continued to rise reaching levels of 1:100,000 in some patients. One patient continued to have rising titers beyond 56 days with serum titers of IgG both to spike and to RBD of >102,000. Neutralizing antibody titers also increased progressively out to 28 days, which was the latest time point available.

- In one patient tested, memory B cells increased from 1.8% to 4.8% of B cells at 28 days post treatment with CPI-006, with serum IgG titers to spike and to RBD of >1:50,000.

- In three of three patients tested to-date, CD4 and CD8 T effector memory cells increased by day 28 post treatment with CPI-006 and these cells were shown to respond specifically to SARS-CoV-2 viral antigens.

- All 10 patients were discharged from the hospital with clinical improvement after a median of four days.

- There were no drug-related toxicity or safety issues reported.

Additional data from the Phase 1 clinical trial is expected to be available in late 2020, including results from the 3.0 and 5.0 mg cohorts and longer follow-up data from the 0.3 and 1.0 mg cohorts. The Company has also submitted for a potential presentation of data from this study at the Society for Immunotherapy of Cancer (SITC) annual meeting in November. In addition, if the study meets its objectives, Corvus intends to work with the FDA to initiate a broader, randomized study that could potentially be adapted into a pivotal study to support a regulatory submission for FDA approval.

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, the Company's ability to develop and advance product candidates into and successfully complete clinical trials, including the Company's Phase 1 clinical trial of CPI-006 for COVID-19. 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, 2020, filed with the Securities and Exchange Commission on July 30, 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; the accuracy of the Company's estimates relating to its ability to initiate and/or complete 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 foreign countries; and 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: September 10, 2020

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