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): November 9, 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 November 9, 2020, Corvus Pharmaceuticals, Inc. ("Corvus" or the "Company") announced that it has completed patient enrollment in its Phase 1 study investigating the potential for CPI-006 to provide a novel immunotherapy approach for hospitalized patients with COVID-19. This novel immunotherapy may provide a therapeutic benefit from the activation of a polyclonal antibody response to the SARS-CoV-2 virus and the induction of long term immunity through active immunization. Updated data from the study is being presented this week in a poster presentation and an oral presentation at the 2020 Society for Immunotherapy of Cancer (SITC) Annual Meeting. The oral presentation will take place on Friday, November 13 at 12:15 pm ET as part of Session 301, which is titled "Hot Topic Symposium: COVID-19 and Cancer." Based on the study data to-date, the Company plans to initiate a pivotal, randomized, double blind study of CPI-006 in hospitalized COVID-19 patients in December with results expected around mid-2021.

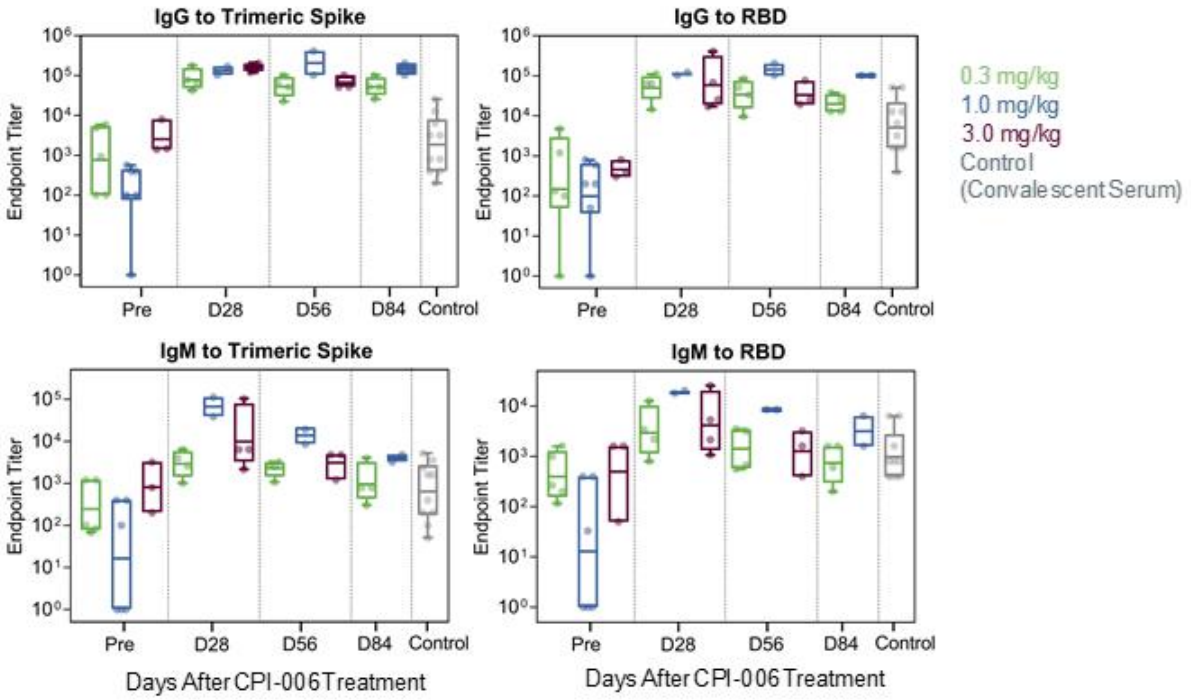
The data presented at SITC include results from 22 patients enrolled in the Phase 1 study utilizing a cut-off date of November 4, 2020. This includes enrollment in all four dosing cohorts of the study (0.3, 1.0, 3.0 and 5.0 mg/kg). All patients received a single dose of CPI-006 administered via a 5-10 minute intravenous (IV) infusion. The median age of the patients was 58 years (range 23-76 years). All of the patients had comorbidities that increased their COVID-19 risk including diabetes, coronary disease, hypertension, obesity, chronic kidney disease, chronic lung disease and/or cancer. 95% of patients were from racial minority populations that are at high risk of COVID-19 complications. The key highlights from the presentation include:

Results Support the Immune Enhancing Role of CPI-006 in COVID-19

- All patients had relatively low titers of anti-SARS-CoV-2 antibodies at the time of hospitalization despite having varying durations of prior COVID-19 symptoms from 1-21 days (median 5 days); all patients had a confirmed COVID-19 diagnosis by positive PCR nasal swab testing.
- All evaluable patients had prompt anti-SARS-CoV-2 antibody responses within 7 days of administration of CPI-006 at all dose levels.
- All patients recovered and were discharged from the hospital at a median of 4 (range 2-23) days.
- As of the November 4, 2020 cut-off date, there were no drug-related toxicity or safety issues reported.

Antibody Response Results

- Four of four evaluable patients that received the 0.3 mg/kg dose had sustained high titers of IgG antibodies to trimeric spike (TS) protein out to 84+ days (one patient 100+ days), without evidence of diminution of response. In these patients, IgM antibody titers peaked at 28-56 days and remained elevated out to 84+ days. Similar trends were seen in IgG and IgM antibody response to receptor binding domain (RBD).
- The geometric mean titers (GMT) for the 0.3, 1.0 and 3.0 mg/kg cohorts are shown in the charts below.
    - A dose response was observed comparing the 3.0 and 1.0 mg/kg dose to the 0.3 mg/kg dose. Higher and more sustained titers of both IgG and IgM to both spike protein and RBD were seen out to 56 days when comparing the 1.0 to 0.3 mg/kg doses. The IgM responses were noteworthy for the sustained prolonged elevation.
    - Antibody responses from 3.0 and 5.0 mg/kg doses appeared similar to the 1.0 mg/kg dose, but the follow up period for such doses was shorter as of the cut-off date.
- In viral neutralization assays, three of three patients developed anti-viral antibody responses out to day 56 that blocked infectivity of receptor bearing cells in a pseudovirus neutralization assay.
- Memory B cells were elevated in 6 of 6 tested patients following treatment with CPI-006. Memory T effector cells were also elevated following treatment and produced interferon-gamma and interleukin-2 in response to SARS-CoV-2 antigen consistent with antigen specific Th1 biasing.



Anti-SARS-COV-2 antibody response (IgG and IgM) to trimeric spike protein and RBD of SARS-CoV-2. Patients received a 0.3, 1.0 or 3.0 mg/kg single dose of CPI-006 and antibody titers were measured at pre-treatment and at days 28, 56 and 84. Data are shown as box and whisker plot with geometric mean and interquartile ranges. Each dot represents a patient. Also shown are titers from convalescent patients serum obtained 28-42 days after recovery from COVID-19.

Polyclonal Antibody Response

- The magnitude and diversity of the polyclonal responses were evaluated by mapping of antibody responses to the subdomains of the TS protein including the N-terminal, RBD, S1 and S2 subdomains. Polyclonality and reactivity to multiple antigenic determinants on the virus were found, which have the potential to lead to viral neutralization and elimination and to reduce the potential for escape due to emergence of mutant forms of the virus. The mapping shows:
  - IgG responses were polyclonal, polyspecific and directed to all subdomains.
  - IgM responses were polyclonal and directed to all subdomains but are preferentially directed to the RBD.

Preclinical Results from Humanized Mouse Studies

Vaccination studies conducted by Corvus in mice bearing human immune cells showed that administration of combinations of CPI-006 with TS protein from the SARS-CoV-2 virus resulted in an antigen specific humoral immune response to the TS protein. No humoral immune response was seen in mice receiving combinations of TS with a control antibody. The responses were specific to the immunizing TS protein as there was no reactivity to other viral proteins. These controlled studies demonstrated that the administration of CPI-006 led to the generation of antigen-specific immune response to the TS protein.

Update on CPI-006 Phase 1/1b Cancer Clinical Trial

Corvus announced that it has completed enrollment in the final cohort of the Phase 1/1b cancer clinical trial. This cohort was designed to evaluate CPI-006 in combination with ciforadenant, the Company's A2A receptor antagonist, and pembrolizumab (triplet cohort). Other cohorts examined CPI-006 monotherapy and in combination with ciforadenant (doublet cohort). Nine patients were enrolled in the triplet cohort, including four patients with renal cell cancer (RCC). All four RCC patients remain on treatment from 2-11+ months and results, as of the November 4, 2020 cut-off date, include one partial response (RECIST) in a patient refractory to previous treatment with nivolumab, ipilimumab and cabozantanib. This patient's tumor was positive for the Adenosine Gene Signature, a biomarker discovered by Corvus that reflects adenosine induced immunosuppression in the tumor. As of the cut-off date, the other three patients remain on study with stable disease.

The results presented at SITC build on the initial data from the first two cohorts (0.3 mg and 1.0 mg doses) of the study that was published online in September 2020. In addition to detailing the initial results, the published manuscript provided additional details on the unique properties of CPI-006 and on the study rationale and design, along with context on the broad potential for CPI-006 for the treatment and prevention of COVID-19.

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 preclinical studies and clinical trials, including the Company's Phase 1/1b clinical trial of CPI-006 for certain cancers, as well as the Company's Phase 1 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 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 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; 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; 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. 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.

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: November 9, 2020

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