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): July 7, 2020

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 (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 | e Form 8-K filing is intended to sir | nultaneously satisfy the fili | ng obligation of the re | gistrant under any o | f the following |
|--|--------------------------------------|-------------------------------|-------------------------|----------------------|-----------------|
| provisions: | | | | | |

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- $\hfill \Box$ 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 | Nasdag 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 [X]

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. [X]

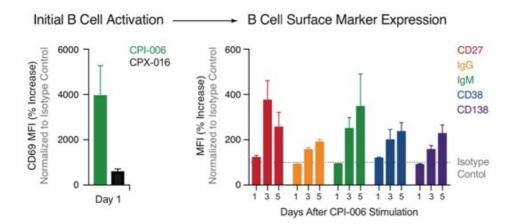
Item 8.01 Other Events.

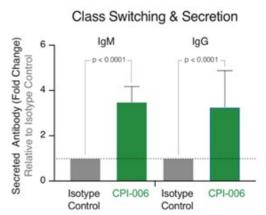
On July 7, 2020, Corvus Pharmaceuticals, Inc. ("Corvus" or the "Company") announced that it has initiated a Phase 1 study to investigate a novel immunotherapy approach for patients with COVID-19. The first cohort of five patients enrolled in the study was treated at Temple University Hospital in Philadelphia, PA. The study is expected to enroll up to 30 patients at several sites in the United States. This follows the U.S. Food and Drug Administration's (FDA) review and acceptance of the Company's investigational new drug (IND) application for the COVID-19 study.

Corvus is studying an agonistic humanized monoclonal antibody, designated as CPI-006, which has demonstrated a potential new approach to immunotherapy of infectious diseases. In both *in vitro* and *in vivo* studies in cancer patients, CPI-006 has demonstrated binding to various immune cells and the inducement of a humoral adaptive immune response – B cell activation and lymphocyte trafficking leading to the production of antigen-specific immunoglobulin (IgM and IgG) antibodies. Administration of CPI-006 has also led to increased levels of memory B cells, which are the cells responsible for long-term immunity. The similar production of antibodies and memory cells to pathogens such as severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus that causes COVID-19, could provide immediate and long-term clinical benefits for patients, including shortened recovery time and improved long-term protective immunity. To the Company's knowledge, Corvus is the only company exploring the potential to induce antibody production via B cell activation for the treatment of COVID-19.

To date, over 90 cancer patients have been treated with CPI-006 in the Corvus Phase 1/1b study, with dosing as high as 24 mg/kg every three weeks. CPI-006 has been well tolerated in these patients and evidence of B cell activation and lymphocyte trafficking was observed in patients that received doses as low as 1 mg/kg. Corvus' study showed that CPI-006 is associated with increases in memory B cells, the emergence of new B cell clones and, in some patients, the production of novel anti-tumor antibodies. These results have been previously reported in a presentation at the Society of Immunotherapy of Cancer annual meeting in 2018 and 2019 and in a presentation at the American Society of Clinical Oncology annual meeting in 2019. CPI-006 was designed to bind to an epitope on an antigen known as CD73. This antigen is known to be involved in lymphocyte migration and activation. CPI-006 binds to a distinct region of on CD73 and behaves as an agonist that serves as a signal to activate certain immune cells. As previously reported, binding of CPI-006 affects B cells, T cells and antigen presenting cells. The collection of observed changes are consistent with enhanced antigen recognition and induction of an adaptive immune response. These results are also supported further by the data set forth below from Corvus' preclinical and Phase 1/1b clinical trial of CPI-006.

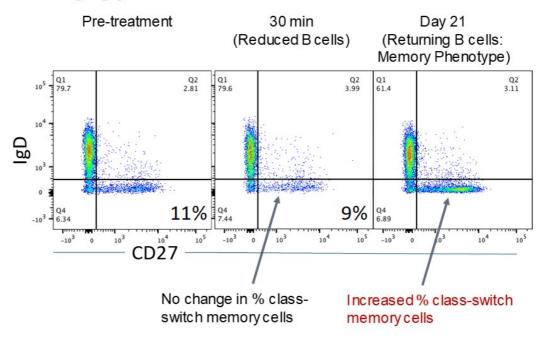
The graph below shows results from an *in vitro* study designed to compare CPI-006 to an anti-CD73 antibody in clinical development by a third party that reacts with a different epitope or region on CD73. Using human blood lymphocytes treated *in vitro*, there was an increase in expression of CD69, a known marker of B cell activation, that occurred following incubation with CPI-006 as compared to incubation with another anti-CD73 antibody, that does not activate B cells. CD69 is the signal for B cells to traffic to lymph nodes. The middle and right panels show that CPI-006 induced markers of B cell differentiation into plasma cells (CD27, CD38 and CD138) and secretion of IgM and IgG.





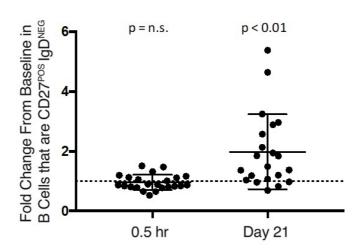
In the Company's Phase 1/1b clinical trial of CPI-006, Corvus measured the levels of B cells at three points in time: pre-treatment, 30 minutes post treatment, and 21 days post treatment. The plots below provide an example from a patient treated with a single dose of CPI-006. Using flow cytometry to quantitate memory B cells, there was a reduction in total B cells at 30 minutes (middle plot), but at day 21, memory B cells represented 29% of the total B cells, compared to approximately 10% prior to the administration of CPI-006.

Peripheral Blood Gated on CD19+ and CD20+ B Cells 6mg/kg patient



The graph below plots the fold-increase of memory B cells, 30 minutes after treatment and 21 days after treatment compared to baseline in several patients receiving 6 mg/kg or more of CPI-006. Each dot represents a patient.

Increased Memory B Cells at Day 21

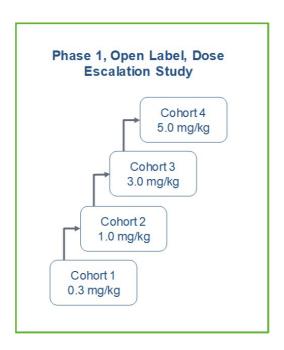


A recently enrolled patient with advanced metastatic non-small cell lung cancer (NSCLC) was diagnosed with concomitant COVID-19 at the time of initiating CPI-006 therapy for cancer. The patient was in a very high risk group for potential progression of COVID-19, including elderly, prior immunosuppressive therapies for cancer and chronic obstructive pulmonary disease as comorbidities. The patient remained asymptomatic from COVID-19 following treatment with CPI-006. Serum antibody testing demonstrated no anti-SARS-CoV-2 antibody at baseline and the development of high titers of anti-SARS-CoV-2 IgG and IgM of >1:100,000 and 1:3,200, respectively, within six weeks of treatment with CPI-006. The patient then tested negative for the virus. The anti-SARS-CoV-2 antibody titers seen in this patient would be considered to be high as recovered patients with serum titers of 1:320 or higher are candidates to donate blood for COVID-19 convalescent plasma therapy. Memory B cells in the blood increased to 30% of total B cells, from 16% previously.

About the Phase 1 Study

The open-label, Phase 1 study is expected to enroll up to 30 COVID-19 patients with mild to moderate symptoms. 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 will also examine safety and other clinical endpoints, including time to resolution of symptoms and duration of hospitalization. Data from this study should be available later this year.

The objective of the study is to show that CPI-006 has the potential to induce the patient to produce an enhanced antibody response to SARS-CoV-2. The expected benefit for patients is the potential eradication of the virus, leading to a better clinical outcome – less severe disease, prevention of complications, and faster recovery – and the potential for long term immunity. If the study meets its objectives, Corvus intends to work with the FDA to initiate a broader, randomized study at a fixed dose of CPI-006 that could potentially be adapted into a pivotal study to support a regulatory submission for FDA approval.



About CPI-006

CPI-006 is a potent humanized monoclonal antibody that reacts with a specific site on CD73. It has demonstrated immunomodulatory activity resulting in activation of lymphocytes, induction of antibody production from B cells and effects on lymphocyte trafficking. Other anti-CD73 antibodies are in development for treatment of cancer. Those antibodies react with a different region of CD73 and are designed to block production of adenosine, which is not involved in the immunomodulatory processes seen with CPI-006.

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 ciforadenant, CPI-006, and CPI-818, 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 clinical trial of CPI-006 for COVID-19, and the impact of COVID-19 and related "shelter in place" orders and other public health guidance measures on the Company's clinical programs and business operations. 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 March 31, 2020, filed with the Securities and Exchange Commission on April 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 forwardlooking 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 foreign countries; the costs of clinical trials may exceed expectations; the Company's ability to raise additional capital; 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.

By: /s/ Leiv Lea

Date: July 7, 2020

Leiv Lea

Chief Financial Officer