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): October 31, 2023

Cocrystal Pharma, Inc.
(Exact name of registrant as specified in its charter)

Delaware	001-38418	35-2528215
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

19805 N. Creek Parkway
Bothell, WA 98011
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (786) 459-1831

N/A
(Former name or former address, if changed since last report.)

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 (see General Instruction A.2. below):

☐ 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	COCP	The Nasdaq Stock Market LLC (The Nasdaq Capital 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 7.01 Regulation FD Disclosure.

On October 31, 2023, Cocrystal Pharma, Inc. (the "Company") issued a press release announcing its receipt of authorization to initiate a Phase 2a human challenge trial in the United Kingdom for its CC-42344 product candidate as a potential treatment for pandemic and seasonal influenza A. A copy of the press release is being furnished as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Press Release issued by Cocrystal Pharma, Inc. on October 31, 2023
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

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.

Dated: October 31, 2023

Cocrystal Pharma, Inc.

By: */s/ James Martin*
Name: James Martin
Title: Chief Financial Officer and Co-Chief Executive Officer

Cocrystal Pharma Receives UK MHRA Authorization to Initiate Its Phase 2a Influenza Human Challenge Trial with Oral PB2 Inhibitor CC-42344

BOTHELL, Wash. (October 31, 2023) – Cocrystal Pharma, Inc. (Nasdaq: COCP) (Cocrystal or the Company) announces receipt of authorization from the United Kingdom Medicines and Healthcare Products Regulatory Agency (MHRA) to initiate a Phase 2a human challenge trial with its broad-spectrum, oral PB2 inhibitor CC-42344 as a potential treatment for pandemic and seasonal influenza A. Cocrystal expects to begin treating influenza-infected subjects in this trial during the fourth quarter of 2023.

In late 2022 Cocrystal reported highly favorable safety and tolerability results in the single-ascending and multiple-ascending dose portions of the healthy volunteer Phase 1 trial conducted in Australia. The Phase 2a single-site, double-blind, placebo-controlled human challenge trial will evaluate the safety, viral and clinical measurements of orally administered CC-42344 in subjects infected with influenza A.

"We are pleased to have met the regulatory requirements of the MHRA to begin this Phase 2a human challenge trial in the UK," said Sam Lee, Ph.D., Cocrystal's President and co-CEO. "Influenza is a major global health threat that may become more challenging to treat due to emergence of highly pathogenic avian influenza viruses and resistance to approved influenza antivirals. The need for new therapeutic and prophylactic treatments is clear. Our encouraging Phase 1 data demonstrated that CC-42344 has a favorable safety profile and is well-tolerated. CC-42344 has the potential to be a best-in-class antiviral treatment for pandemic and seasonal influenza infections."

"We are closely working with a world leading clinical research organization that is experienced in testing infectious and respiratory disease antivirals using human challenge clinical trials," said James Martin, Cocrystal's CFO and Co-CEO. "Receiving authorization to move ahead with our Phase 2a trial is a major step in our quest to bring CC-42344 to market and make a meaningful contribution to improving health and reducing the cost of care."

About Seasonal Influenza

Each year there are approximately one billion cases of seasonal influenza worldwide, 3-5 million severe illnesses and up to 650,000 deaths, according to the World Health Organization. On average about 8% of the U.S. population contracts influenza each seasor. In addition to the health risk, influenza is responsible for approximately $10.4 billion in direct costs for hospitalizations and outpatient visits for adults in the U.S. annually.

About CC-42344

CC-42344 was discovered using Cocrystal's proprietary structure-based drug discovery platform technology and is a novel approach to treating pandemic and seasonal influenza A. *In vitro* data show that CC-42344 is highly active against drug-resistant influenza A strains with a high barrier to resistance, while also demonstrating favorable pharmacokinetic and safety profiles.

About Cocrystal Pharma, Inc.

Cocrystal Pharma, Inc. is a clinical-stage biotechnology company discovering and developing novel antiviral therapeutics that target the replication process of influenza viruses, coronaviruses (including SARS-CoV-2), hepatitis C viruses and noroviruses. Cocrystal employs unique structure-based technologies and Nobel Prize-winning expertise to create first- and best-in-class antiviral drugs. For further information about Cocrystal, please visit www.cocrystalpharma.com.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements regarding the initiation and characteristics of a Phase 2a study for CC-42344 and the potential efficacy and clinical benefits of such product candidate and the demand for such a product. The words "believe," "may," "estimate," "continue," "anticipate," "intend," "should," "plan," "could," "target," "potential," "is likely," "will," "expect" and similar expressions, as they relate to us, are intended to identify forward-looking statements. We have based these forward-looking statements largely on our current expectations and projections about future events. Some or all of the events anticipated by these forward-looking statements may not occur. Important factors that could cause actual results to differ from those in the forward-looking statements include, but are not limited to, the risks arising from manufacturing and research delays arising labor shortages and other factors, the ability of our Clinical Research Organization partner to recruit volunteers for, and to proceed with, the Phase 2a clinical study for CC-42344, general risks arising from conducting a clinical trial, receipt of regulatory approvals for future trials, regulatory changes, development of effective treatments and/or vaccines by competitors, including as part of the programs financed by the governmental authorities, and potential mutations in a virus we are targeting which may result in variants that are resistant to a product candidate we may develop. Further information on our risk factors is contained in our filings with the SEC, including our Annual Report on Form 10-K for the year ended December 31, 2022. Any forward-looking statement made by us herein speaks only as of the date on which it is made. Factors or events that could cause our actual results to differ may emerge from time to time, and it is not possible for us to predict all of them. We undertake no obligation to publicly update any forward-looking statement, whether as a result of new information, future developments or otherwise, except as may be required by law.

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