# 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): January 4, 2024

# 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<br>Bothell, WA | 98011 |
|---|---|
| (Address of principal executive offices) | (Zip Code) |

Registrant's telephone number, including area code: (877) 262-7123

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<br>(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 January 4, 2024, Cocrystal Pharma, Inc. (the "Company") issued a press release providing updates on the clinical development for its CDI-988 product candidate as a potential treatment for pandemic norovirus and coronavirus and 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 January 4, 2024 |
| 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: January 4, 2024

**Cocrystal Pharma, Inc.**

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

**Cocrystal Pharma Provides an Update on the Clinical Development of its Novel, Broad-Spectrum Antiviral Investigational Candidates**

**BOTHELL, Wash. (January 4, 2024)** – Cocrystal Pharma, Inc. (Nasdaq: COCP) ("Cocrystal" or the "Company") provides an update on the clinical development of its oral first-in-class pan-norovirus and pan-coronavirus dual protease inhibitor CDI-988 and its oral PB2 inhibitor CC-42344 for the treatment of pandemic and seasonal influenza A. CDI-988 and CC-42344 were specifically designed and developed using Cocrystal's unique structure-based drug discovery technology platform to be effective on a broad range of viruses causing these diseases.

"We are encouraged that the preliminary data of the ongoing Phase 2a and Phase 1 studies showed CC-42344 and CD-988 were well-tolerated with favorable safety profiles," said Sam Lee, Ph.D., Cocrystal's President and co-CEO. "We see great promise with both of these drug candidates as potential effective oral treatments for highly contagious, pandemic viruses, while also providing significant market opportunities for Cocrystal."

CDI-988 targets a highly conserved region in the active site of the main 3CL protease required for viral RNA replication for pandemic norovirus and coronaviruses, including SARS-CoV-2. CDI-988 is being evaluated for safety and pharmacokinetics in a randomized, double-blinded, placebo-controlled Phase 1 study in healthy subjects being conducted in Australia. The Company reports favorable preliminary data from the single-ascending dose cohorts of the clinical study. Cocrystal expects to report topline results from the Phase 1 study this year.

CC-42344 binds to a highly conserved PB2 site of the influenza A polymerase complex and exhibits a novel mechanism of action that inhibits viral replication. A randomized, double-blind, placebo-controlled Phase 2a clinical study with CC-42344 is underway in the United Kingdom. The Company reports favorable tolerability and safety in the first cohort of the Phase 2a influenza A challenge study and expects to report topline results from the Phase 2a clinical study this year. In 2022 Cocrystal reported favorable safety and tolerability results in the healthy volunteer Phase 1 study with CC-42344 conducted in Australia.

**About Norovirus**

Although norovirus is a worldwide public health problem, there are no effective treatments or vaccines. Norovirus afflicts an estimated 685 million people annually at an estimated societal cost of $60 billion. About 200 million cases are seen among children under 5 years old, leading to an estimated 50,000 child deaths every year, mostly in developing countries, according to the Centers for Disease Control and Prevention (CDC). CDI-988 *in vitro* studies showed potent broad-spectrum antiviral activity against a panel of pandemic GII.4 norovirus proteases, which have caused the majority of norovirus outbreaks worldwide since 2002, and a favorable pharmacokinetic property targeting the gastrointestinal tract.

**About COVID-19**

COVID-19 hospitalizations have recently increased in the U.S. with the new JN.1 variant responsible for about 20% of these cases. Driven by the anticipated emergence of new COVID-19 variants, the global COVID-19 therapeutics market is estimated to exceed $16 billion by the end of 2031. The ability of someone with no symptoms to transmit infection to another person has heightened the public health challenge of COVID-19. CDI-988 exhibited superior *in vitro* potency against SARS-CoV-2 with activity maintained against variants of concern. By targeting the viral replication protease, Cocrystal believes it is possible to develop an effective treatment for all coronaviruses, including COVID-19 and its variants, as well as for Severe Acute Respiratory Syndrome (SARS) and Middle East Respiratory Syndrome (MERS).



**About Seasonal Influenza**

Each year there are approximately 1 billion cases of seasonal influenza worldwide, with 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 season. 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 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) noroviruses and hepatitis C viruses. 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 promise and potential of the two product candidates, the clinical development of CC-42344 as a product candidate for oral antiviral inhibitor for the treatment of pandemic and seasonal influenza A and the Phase 2a study for such product candidate, CC-988 as a product candidate for dual oral antiviral inhibitor for the treatment of coronavirus and norovirus and the Phase 1 study for such product candidate, the potential efficacy and clinical benefits of, and market for, such product candidates, and the expected results and topline data from these clinical trials in 2024. 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, risks relating to our ability to proceed with the studies including recruiting volunteers and procuring materials for such studies by our clinical research organizations and vendors, and the results of such studies. 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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