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): March 28, 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 Bothell, WA	98011
(Address of principal executive offices)	(Zip Code)

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

(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:

☐ 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))

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. ☐

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)

Item 2.02 Results of Operations and Financial Condition

On March 28, 2024, Cocrystal Pharma, Inc. (the "Company") issued a press release announcing its results of operations for the fiscal year ended December 31, 2023. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information contained in this Item 2.02, including Exhibit 99.1 attached hereto, is being furnished and shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, or otherwise subject to the liabilities of that section. Furthermore, the information contained in this Item 2.02 or Exhibit 99.1 shall not be deemed to be incorporated by reference into any registration statement or other document filed pursuant to the Securities Act of 1933, except as shall be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit	Description
99.1	Press Release dated March 28, 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.

Cocrystal Pharma, Inc.

Date: March 28, 2024

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

Cocrystal Pharma Reports 2023 Financial Results and Provides Updates on its Antiviral Drug-Development Programs

- *FDA feedback following the Company's submission of a Pre-IND briefing package improves clarity on regulatory requirements for Phase 2b influenza A clinical trial with oral CC-42344, a broad-spectrum PB2 inhibitor*
- *Topline data expected in 2024 from Phase 2a influenza A human challenge study and Phase 1 study with oral CDI-988, the first potential dual coronavirus-norovirus oral antiviral*
- *Initiation of Phase 1 study expected in 2024 with inhaled CC-42344, a potential influenza treatment and post-exposure prophylactic*

BOTHELL, Wash. (March 28, 2024) – Cocrystal Pharma, Inc. (Nasdaq: COCP) (Cocrystal or the Company) reports financial results for the 12 months ended December 31, 2023, and provides updates on its antiviral product pipeline, upcoming milestones and business activities.

"We are highly encouraged by the FDA's feedback to our Pre-Investigational New Drug (Pre-IND) package, which provides greater clarity on the regulatory requirements for a planned Phase 2b clinical trial with our novel broad-spectrum oral PB2 inhibitor *CC-42344* for pandemic and seasonal influenza A," said Sam Lee, Ph.D., President and co-CEO of Cocrystal. "This is a major step in the clinical and regulatory process for this program. We plan to file an IND for late-stage clinical development of oral *CC-42344* that includes data from our ongoing Phase 2a human challenge study, which are expected later this year.

"During 2024 we also expect to initiate a Phase 1 study in healthy volunteers with inhaled*CC-42344* as a potential prophylactic and therapeutic for influenza A. Our inhaled formulation of *CC-42344* has shown the ability to directly target influenza-infected respiratory epithelial cells in lung, allowing for higher accumulation of drug in the pulmonary system and potentially producing a rapid clinical response while reducing potential systemic side effects," he added. "Also during the coming year we expect topline data from the ongoing first-in-human study with our pan-coronavirus and pan-norovirus oral protease inhibitor *CDI-988*, which is expected to serve as a Phase 1 study for both indications."

"All our programs target high-value unmet indications with novel, broad-spectrum, best-in-class antiviral candidates whose design and development uses our proprietary structure-based drug discovery platform technology," said James Martin, CFO and co-CEO. "I'm pleased to report that under our cost-efficient business model, we believe our cash position is sufficient to fund current operations including planned clinical studies beyond the next 12 months."

Antiviral Product Pipeline Overview

We are developing therapeutics that inhibit the viral replication function of RNA viruses that cause acute and chronic diseases. Our drug-discovery process focuses on the highly conserved regions of the viral enzymes and inhibitor-enzyme interactions at the atomic level. By designing and selecting antiviral drug candidates that interrupt the viral replication process and have specific binding characteristics, we seek to develop drugs that are effective against the virus and mutations of the virus, and also have reduced off-target interactions that may cause undesirable side effects. Our drug discovery process differs from traditional, empirical medicinal chemistry approaches that often require iterative high-throughput compound screening and lengthy hit-to-lead processes.

Influenza Programs

Influenza is a severe respiratory illness that is caused by the influenza A or B virus and results in disease outbreaks mainly during the winter months. Influenza is a major global health threat that may become more challenging to treat in the future due to the emergence of highly pathogenic avian influenza viruses and resistance to approved influenza antivirals.

Each year there are approximately 1 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 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.

- *Pandemic and Seasonal Influenza A*
  - Our novel PB2 inhibitor *CC-42344* has shown excellent *in vitro* antiviral activity against influenza A strains including pandemic and seasonal strains, as well as strains that are resistant to Tamiflu® and Xofluza®.
  - In March 2022 we initiated enrollment in a randomized, double-blind, dose-escalating Phase 1 study to evaluate the safety, tolerability and pharmacokinetics (PK) of oral *CC-42344* in healthy adults.
  - In July 2022 we reported PK results from the single-ascending dose portion of the study that support once-daily dosing.
  - In December 2022 we reported favorable safety and tolerability results from the oral *CC-42344* Phase 1 study.
  - In October 2023 we announced authorization from the United Kingdom Medicines and Healthcare Products Regulatory Agency to conduct a Phase 2a human challenge study.
  - In December 2023 we began treating influenza-infected subjects in the randomized, double-blind, placebo-controlled Phase 2a human challenge study to evaluate the safety, tolerability, viral and clinical measurements of influenza A infection in subjects treated with oral CC-42344.
  - In March 2024 we received feedback from the FDA on a Pre-IND package improving clarity on clinical trial design, drug manufacturing and nonclinical studies necessary to file a Phase 2b trial design.
  - Preclinical development is underway with inhaled *CC-42344* as a potential therapeutic and post-exposure prophylaxis for influenza A. *CC-42344* has exhibited superior pulmonary exposure in preclinical testing. We expect to begin a Phase 1 clinical study with inhaled *CC-42344* in Australia in 2024.
- *Influenza A/B Program*
  - Preclinical lead optimization of replication inhibitor antiviral candidates is underway.

COVID-19 and Other Coronavirus Programs

By targeting viral replication enzymes and protease, we believe it is possible to develop effective treatments for all diseases caused by coronaviruses including COVID-19, Severe Acute Respiratory Syndrome (SARS) and Middle East Respiratory Syndrome (MERS). Our main SARS-CoV-2 protease inhibitors showed potent *in vitro* pan-viral activity against common human coronaviruses, rhinoviruses and respiratory enteroviruses that cause the common cold, as well as against noroviruses that can cause symptoms of acute gastroenteritis. 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.

- *Oral Protease Inhibitor CDI-988*

- In October 2022 we announced the selection of *CDI-988* as our lead candidate for development as a potential oral treatment for SARS-CoV-2. *CDI-988* exhibited superior *in vitro* potency against SARS-CoV-2 with activity maintained against variants of concern, and demonstrated a safety profile and PK properties that support once-daily dosing.

- In May 2023 we announced approval of our application to the Australian regulatory agency for a randomized, double-blind, placebo-controlled Phase 1 study to evaluate the safety, tolerability and PK of oral *CDI-988* in healthy volunteers.
- In August 2023 we announced the selection of *CDI-988* as our lead oral candidate for norovirus, in addition to coronavirus.
- In September 2023 we dosed the first subject in our dual norovirus-coronavirus oral *CDI-988* study, which is expected to serve as a Phase 1 study for both indications.
- We expect topline data from the Phase 1 study with *CDI-988* in 2024.

Norovirus Program

Norovirus is a highly contagious infection and is the most common cause of acute gastroenteritis, accounting fonearly one in five cases. According to the Centers for Disease Control and Prevention (CDC), an estimated 685 million cases and an estimated 200,000 deaths are attributed to norovirus each year worldwide, with an estimated societal cost of $60 billion.

3CL inhibitor *CDI-988* has shown pan-viral activity against multiple norovirus strains, including the genogroup II, genotype 4 (GII.4) norovirus strain that is responsible for major norovirus outbreaks. By targeting viral replication, we believe it is possible to develop an effective treatment or short-term prophylactic for closed environments for all genogroups of norovirus.

- In August 2023 we announced our selection of the novel broad-spectrum oral 3CL protease inhibitor *CDI-988* as our lead potential oral treatment for norovirus, in addition to coronavirus.
- In September 2023 we began subject dosing in a first-in-human study in healthy volunteers in Australia. The randomized, double-blind, placebo-controlled study to evaluate the safety, tolerability and PK of oral CDI-988 in healthy volunteers is expected to serve as a Phase 1 study for both indications.
- We expect topline data from the Phase 1 study with *CDI-988* in 2024.

2023 Financial Results

Research and development (R&D) expenses for 2023 were $15.2 million, compared with $12.4 million for 2022. The increase was primarily due to advancing influenza candidate *CC-42344* into a Phase 2a study and advancing the dual norovirus-coronavirus candidate*CDI-988* into a Phase 1 study. General and administrative (G&A) expenses for 2023 were $6.0 million, compared with $5.7 million for 2022.

During 2023 the Company received $2.6 million related to litigation with an insurer, which included a $1.6 million refund from the registry of theUnited States Court of Appeals for the Third Circuit, reflecting the recovery of funds following a successful appeal, and $1.0 million in a settlement agreement with the insurer.

Interest income for 2023 was $640,000, compared with interest expense of $2,000 for 2022. The interest income in 2023 was related to interest earned from cash held in banks and deposits with the court registry, and the interest expense in 2022 was related to finance lease agreements.

The net loss for 2023 was $18.0 million, or $1.87 per share, compared with the net loss for 2022 of $38.8 million, or $4.77 per share, which included a $19.1 million non-cash impairment-loss of goodwill.

Cocrystal reported unrestricted cash as of December 31, 2023 of $26.4 million, compared with $37.1 million as of December 31, 2022. Net cash used in operating activities for 2023 was $14.7 million, compared with $21.4 million for 2022. The Company had working capital of $25.0 million and 10.2 million common shares outstanding as of December 31, 2023.

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 our plans for the future development of preclinical and clinical drug candidates, our expectations regarding future characteristics of the product candidates we develop, the expected time of achieving certain value-driving milestones in our programs, including preparation, commencement and advancement of clinical studies for certain product candidates in 2024, the viability and efficacy of potential treatments for diseases our product candidates are designed to treat, expectations for the markets for certain therapeutics, our ability to execute our clinical and regulatory goals and deploy regulatory guidance towards future studies, the expected sufficiency of our cash balance to advance our programs and fund our planned operations, and our liquidity. 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 and uncertainties arising from the high interest rates in response to inflation, uncertainty in the financial markets, the possibility of a recession and geopolitical conflict in Ukraine and Israel on our Company, our collaboration partners, and on the U.S., UK, Australia and global economies, including manufacturing and research delays arising from raw materials and labor shortages, supply chain disruptions and other business interruptions on our ability to proceed with studies as well as similar problems with our vendors and our current and any future clinical research organization (CROs) and contract manufacturing organizations (CMOs), the ability of our CROs to recruit volunteers for, and to proceed with, clinical studies, our and our collaboration partners’ technology and software performing as expected, financial difficulties experienced by certain partners, the results of any current and future preclinical and clinical studies, general risks arising from clinical studies, receipt of regulatory approvals, regulatory changes, and potential development of effective treatments and/or vaccines by competitors, including as part of the programs financed by the U.S. government, potential mutations in a virus we are targeting that may result in variants that are resistant to a product candidate we 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, 2023. 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.

Investor Contact:

LHA Investor Relations
Jody Cain

310-691-7100
jcain@lhai.com

Media Contact:

JQA Partners
Jules Abraham
917-885-7378
Jabraham@jqapartners.com

Financial Tables to follow

COCRYSTAL PHARMA, INC.

CONSOLIDATED BALANCE SHEETS
(in thousands)

	December 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash	$ 26,353	$ 37,144
Restricted cash	75	75
Tax credit receivable	890	716
Prepaid expenses and other current assets	1,773	2,243
Total current assets	29,091	40,178
Property and equipment, net	271	342
Deposits	46	46
Operating lease right-of-use assets, net (including $42 and $99 to related party)	1,851	274
Total assets	$ 31,259	$ 40,840
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 3,022	$ 976
Current maturities of finance lease liabilities	-	7
Current maturities of operating lease liabilities (including $42 and $59 to related party)	240	233
Total current liabilities	3,262	1,216
Long-term liabilities:		
Operating lease liabilities (including $0 and $42 to related party)	1,613	57
Total long-term liabilities	1,613	57
Total liabilities	4,875	1,273
Commitments and contingencies		
Stockholders' equity:		
Common stock $0.001 par value; 150,000 shares authorized as of December 31, 2023 and December 31, 2022, respectively; 10,174 and 8,143 shares issued and outstanding as of December 31, 2023 and December 31, 2022, respectively	10	8
Additional paid-in capital	342,288	337,489
Accumulated deficit	(315,914)	(297,930)
Total stockholders' equity	26,384	39,567
Total liabilities and stockholders' equity	$ 31,259	$ 40,840

COCRYSTAL PHARMA, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS
(unaudited)
(in thousands, except per share data)

	December 31,	
	2023	2022
Operating expenses:		
Research and development	$ 15,169	$ 12,392
General and administrative	5,990	5,745
Legal settlement	(2,600)	1,600
Impairments	-	19,092
Total operating expenses	18,559	38,829
Loss from operations	(18,559)	(38,829)
Other (expense) income:		
Interest income (expense), net	640	(2)
Change in fair value of derivative liabilities	-	12
Foreign exchange loss	(65)	(18)
Total other income (expense), net	575	(8)

Net loss	$ (17,984)	$ (38,837)
Net loss per common share:		
Loss per share, basic and diluted	$ (1.87)	$ (4.77)
Weighted average number of common shares outstanding, basic and diluted	9,651	8,143

# # #