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 13, 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.): n/a

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 November 13, 2024, Cocrystal Pharma, Inc. (the "Company") issued a press release announcing its results of operations for the fiscal quarter ended September 30, 2024. 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 November 13, 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: November 13, 2024

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

Exhibit 99.1

Cocrystal Pharma Reports Third Quarter 2024 Financial Results and Provides Updates on its Antiviral Drug-Development Programs

BOTHELL, Wash. (November 13, 2024) – Cocrystal Pharma, Inc. (Nasdaq: COCP) ("Cocrystal" or the "Company") reports financial results for the three and nine months ended September 30, 2024, and provides updates on its antiviral product pipeline, upcoming milestones and business activities.

"The coming months are critically important to Cocrystal as we expect to report topline results from two ongoing clinical studies with our best-in-class antiviral candidates in major medical indications," said Sam Lee, Ph.D., President and co-CEO of Cocrystal. "In the Phase 2a influenza A challenge study with our oral PB2 inhibitor *CC-42344,* we expect to report topline results before year end. Earlier this year, we received feedback from the U.S. Food and Drug Administration (FDA) on a Pre-IND package that improves our clarity on the regulatory path and requirements for the late-stage influenza A clinical study we plan to conduct in the U.S.

"The multiple-ascending dose portion in our Phase 1 pan-norovirus/pan-coronavirus study with oral protease inhibitor*CDI-988* is underway and we are on track to report topline results in late 2024 or early 2025," he added. "We view the development of an effective antiviral for norovirus as a significant opportunity for Cocrystal. There is no approved vaccine or antiviral for norovirus, which is highly contagious and the most common cause of acute gastroenteritis. In *in vitro* studies, *CDI-988* exhibited pan-viral activity against multiple norovirus strains, including the strain that is responsible for major outbreaks."

"Our significant clinical progress so far this year puts us on track for an active 2025," said James Martin, CFO and co-CEO of Cocrystal. "I'm pleased to report that based on our currently projected expenditures and our cost-efficient business model, we expect our cash will be sufficient to fund the advancement of our planned development programs through the coming 12 months."

Antiviral Product Pipeline Overview

We apply our proprietary structure-based drug discovery platform technology for developing broad-spectrum antivirals that inhibit viral replication. By designing and selecting antiviral drug candidates that target the highly conserved regions of the viral enzymes, we seek to develop drugs that are effective against the virus and mutations of the virus, and also reduce 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 major global health threat that may become more challenging to treat 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. On average, about 8% of the U.S. population contracts influenza each season. In addition to the health risk, influenza is responsible for an estimated $11.2 billion in direct and indirect costs in the U.S. annually.

- *Oral CC-42344 for the treatment of pandemic and seasonal Influenza A infections*
  - Our novel PB2 inhibitor *CC-42344* showed excellent *in vitro* antiviral activity against pandemic and seasonal influenza A strains, as well as strains that are resistant to Tamiflu® and Xofluza®.
  - In December 2022 we reported favorable safety and tolerability results from the oral *CC-42344* Phase 1 study.
  - In December 2023 we began a randomized, double-blind, placebo-controlled Phase 2a human challenge study to evaluate the safety, tolerability, viral and clinical measurements of *CC-42344* in influenza A-infected subjects in the United Kingdom, following authorization from the UK Medicines and Healthcare Products Regulatory Agency (MHRA).
  - In May 2024 we completed enrollment in the Phase 2a human challenge study.
  - In June 2024 we reported that *in vitro* studies demonstrated *CC-42344* inhibits the activity of the new highly pathogenic avian influenza A (H5N1) PB2 protein recently identified in humans exposed to infected dairy cows.
  - We expect to report topline results from the Phase 2a human challenge study by yearend and plan to file an IND application in 2025 to conduct a late-stage study in the U.S.

- *Inhaled CC-42344 for the therapeutic and prophylactic treatment of pandemic and seasonal Influenza A infections*
  - Our preclinical testing showed superior pulmonary pharmacology with *CC-42344* including high exposure to drug and a long half-life.
  - We completed *CC-42344* inhalation formulation development.
  - We initiated GLP toxicology studies.

- *Influenza A/B Program*
  - Our work to develop a preclinical lead of novel influenza replication inhibitors is underway.

Norovirus Program

Norovirus is a highly contagious infection and is the most common cause of acute gastroenteritis. Worldwide, norovirus causes about one out of five cases of acute gastroenteritis that leads to diarrhea and vomiting. An estimated 685 million cases and an estimated 50,000 child deaths are attributed to norovirus each year worldwide, with an estimated societal cost of $60 billion. By targeting viral replication, we believe it is possible to develop an effective treatment and/or short-term prophylactic for closed environments for all genogroups of norovirus.

- *Oral pan-viral protease inhibitor CDI-988 for the treatment of norovirus and coronavirus infections*
  - Our novel broad-spectrum protease inhibitor *CDI-988* is being evaluated as a potential oral treatment for noroviruses and coronaviruses.
  - *CDI-988* has shown *in vitro* pan-viral activity against multiple norovirus strains, including the genogroup II, genotype 4 (GII.4) norovirus strain that is responsible for major norovirus outbreaks.
  - 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 pharmacokinetics (PK) of oral *CDI-988* in healthy volunteers.
  - In August 2023 we announced our selection of *CDI-988* as our lead for the oral treatment for norovirus, in addition to coronavirus.

- In September 2023 we began dosing subjects in a first-in-human study in healthy volunteers with oral *CDI-988.*
- In July 2024 we reported favorable safety and tolerability results from the single-ascending dose cohort in the Phase 1 study.
- In September 2024 we advanced *CDI-988* into the multiple-ascending dose cohort of the Phase 1 study.
- We expect to report topline results from the *CDI-988* Phase 1 study in late 2024 or early 2025.

COVID-19 and Other Coronavirus Programs

By targeting viral replication enzymes and proteases, we believe it is possible to develop effective treatments for all diseases caused by coronaviruses including COVID-19 and its variants, Severe Acute Respiratory Syndrome (SARS) and Middle East Respiratory Syndrome (MERS). *CDI-988* showed potent *in vitro* pan-viral activity against common human coronaviruses, rhinoviruses and respiratory enteroviruses, as well as against noroviruses. The global COVID-19 therapeutics market is estimated to exceed $16 billion by the end of 2031.

- *Oral pan-viral protease inhibitor CDI-988 for the treatment of coronaviruses and noroviruses*

  - *CDI-988* exhibited superior *in vitro* potency against SARS-CoV-2 and demonstrated a favorable safety profile and PK properties.
  - In September 2023 we dosed the first subject in our dual pan-norovirus/pan-coronavirus oral *CDI-988* study, which is expected to serve as a Phase 1 study for both indications.
  - In July 2024 we reported favorable safety and tolerability results from the single-ascending dose cohort in the Phase 1 study.
  - In September 2024 we advanced *CDI-988* into the multiple-ascending dose cohort of the Phase 1 study.
  - We expect to report topline results from the *CDI-988* Phase 1 study in late 2024 or early 2025.

Third Quarter Financial Results

Research and development (R&D) expenses for the third quarter of 2024 were $3.2 million, compared with $4.2 million for the third quarter of 2023, with the decrease primarily due to lower clinical study expenses. General and administrative (G&A) expenses for the third quarters of 2024 and 2023 remained relatively stable at $1.8 million.

The net loss for the third quarter of 2024 was $4.9 million, or $0.49 per share, compared with a net loss for the third quarter of 2023 of $4.2 million, or $0.41 per share, that included a $1.6 million payment to the Company in 2023 for a legal settlement.

Nine Month Financial Results

R&D expenses for the first nine months of 2024 were $10.5 million, compared with $10.9 million for the first nine months of 2023. G&A expenses for the first nine months of 2024 were $4.1 million, compared with $4.6 million for the first nine months of 2023.

The net loss for the first nine months of 2024 was $14.2 million, or $1.40 per share, compared with a net loss for the first nine months of 2023 of $13.5 million, or $1.43 per share.

Cocrystal reported unrestricted cash as of September 30, 2024 of $13.0 million, compared with $26.4 million as of December 31, 2023. Net cash used in operating activities for the first nine months of 2024 was $13.3 million, compared with $11.3 million for the first nine months of 2023. The Company had working capital of $12.3 million and 10.2 million common shares outstanding as of September 30, 2024.

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 and 2025, 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, and the expected sufficiency of our cash balance to advance our programs and fund our planned operations. 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 future inflation, potential future increases in interest rates uncertainty in the financial markets, the possibility of a recession, and geopolitical conflict including 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 including potential downward pressure on government spending on healthcare in the wake of the recent presidential election in the U.S., the impact of the recent U.S. presidential election on regulation affecting the FDA and other healthcare agencies and potential staffing issues, 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.

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Financial Tables to follow

COCRYSTAL PHARMA, INC.

CONSOLIDATED BALANCE SHEETS
(in thousands)

	September 30, 2024 (unaudited)	December 31, 2023
Assets		
Current assets:		
Cash	$ 13,020	$ 26,353
Restricted cash	75	75
Tax credit receivable	652	890
Prepaid expenses and other current assets	509	1,773
Total current assets	14,256	29,091
Property and equipment, net	181	271
Deposits	29	46
Operating lease right-of-use assets, net (including $163 and $42 respectively, to related party)	1,767	1,851
Total assets	$ 16,233	$ 31,259
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 1,655	$ 3,022
Current maturities of operating lease liabilities (including $55 and $42 respectively, to related party)	293	240
Total current liabilities	1,948	3,262
Long-term liabilities:		
Operating lease liabilities (including $163 and $0 respectively, to related party)	1,582	1,613
Total liabilities	3,530	4,875
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.001 par value 100,000 and 150,000 shares authorized as of September 30, 2024, and December 31, 2023; 10,174 shares issued and outstanding as of September 30, 2024 and December 31, 2023	10	10
Additional paid-in capital	342,845	342,288
Accumulated deficit	(330,152)	(315,914)
Total stockholders' equity	12,703	26,384
Total liabilities and stockholders' equity	$ 16,233	$ 31,259

COCRYSTAL PHARMA, INC.

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

	Three months ended September 30,		Nine months ended September 30,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	3,242	4,194	10,500	10,902
General and administrative	1,800	1,849	4,148	4,591
Legal settlement	-	(1,600)	-	(1,600)
Total operating expenses	5,042	4,443	14,648	13,893
Loss from operations	(5,042)	(4,443)	(14,648)	(13,893)
Other income (expense):				
Interest income (expense), net	111	320	482	460
Foreign exchange loss	(8)	(42)	(72)	(87)
Total other expense, net	103	278	410	373
Net loss	$ (4,939)	$ (4,165)	(14,238)	(13,520)
Net loss per common share, basic and diluted	$ (0.49)	$ (0.41)	(1.40)	(1.43)
Weighted average number of common shares, basic and diluted	10,174	10,153	10,174	9,461

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