March 31, 2025

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

BOTHELL, Wash., March 31, 2025 (GLOBE NEWSWIRE) -- Cocrystal Pharma, Inc. (Nasdaq: COCP) ("Cocrystal" or the "Company") reports financial results for the 12 months ended December 31, 2024, and provides updates on its antiviral product pipeline, upcoming milestones and business activities.

"Our novel, potent antiviral compounds for norovirus, influenza and coronavirus address critical gaps in global health where effective treatments or vaccines are currently lacking," said Sam Lee, Ph.D., President and co-CEO of Cocrystal. "We plan to initiate a norovirus human challenge study in the U.S. later this year to evaluate our pan-viral protease inhibitor *CDI-988* for the potential treatment and prevention of norovirus infection. The big surge in reported norovirus outbreaks is possibly due to norovirus variants switching from GII.4 to GII.17, as well as increased social gathering after the COVID-19 pandemic. Norovirus is the most common cause of acute gastroenteritis and there are no approved therapeutics or vaccines, making it a compelling target.

"We are optimistic that our oral PB2 inhibitor *CC-42344* will have potential as a treatment for seasonal influenza A infection and pandemic avian influenza," he added. "Following the unexpected low infection rate from the Phase 2a challenge study that precluded us from obtaining meaningful human efficacy data, we plan to continue the influenza challenge study."

"News coverage in recent months of norovirus and avian flu outbreaks underscore the urgent need for new antiviral solutions," said James Martin, CFO and co-CEO of Cocrystal. "We are advancing our first- and best-in-class antiviral drug compounds that were designed using our Nobel Prize-winning structure-based technologies for these high-value viral targets that address multibillion-dollar markets."

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 candidates that target highly conserved regions of the viral enzymes, we seek to develop drugs that are effective against the virus and mutations of the virus, while reducing 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*
  - 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 highly pathogenic avian influenza A (H5N1) PB2 protein identified in humans exposed to infected dairy cows.
  - In December 2024 we announced a plan to extend the*CC-42344* human challenge study due to unexpectedly low influenza infection among study participants.

- *Inhaled CC-42344 as prophylaxis and treatment for pandemic and seasonal influenza A*

  - Our preclinical testing showed superior pulmonary pharmacology with *CC-42344* including high exposure to drug and a long half-life.
  - We have completed *CC-42344* inhalation formulation development and GLP toxicology studies.

- *Influenza A/B program*

  - Our efforts to develop a preclinical lead of novel influenza replication inhibitors are ongoing.

Norovirus Program

Norovirus symptoms can include severe nausea, vomiting and diarrhea. An estimated 685 million cases and an estimated 50,000 child deaths worldwide are attributed to norovirus each year, with an estimated societal cost of $60 billion. By targeting viral replication, we believe it is possible to develop an effective treatment and/or prophylaxis for closed environments for all genogroups of norovirus.

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

- 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.
- 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 compound for the oral treatment for noroviruses, in addition to coronaviruses.
- In July 2024 we reported favorable safety and tolerability results from the single-ascending dose cohorts in the Phase 1 study.
- In December 2024 we reported favorable safety and tolerability results from the multiple-ascending dose cohorts of the Phase 1 study and the addition of a higher-dose cohort.
- We expect to report topline results from the high-dose healthy volunteer cohort with *CDI-988* in the second quarter of 2025.
- We plan to initiate a human challenge study in the U.S. in 2025 to evaluate *CDI-988* as a norovirus treatment and prophylaxis.

SARS-CoV-2 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 SARS-CoV-2 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 annually 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 healthy 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 December 2024 we reported favorable safety and tolerability results from the multiple-ascending dose cohorts of the Phase 1 study and the addition of a higher-dose cohort.
  - We expect to report topline results from the higher dose cohort in the *CDI-988* Phase 1 study in the second quarter of 2025.

2024 Financial Results

Research and development (R&D) expenses for 2024 were $12.5 million, compared with $15.2 million for 2023. The decrease was primarily due to the timing of clinical study costs. General and administrative (G&A) expenses for 2024 were $5.3 million, compared with $6.0 million for 2023, with the $0.7 million decrease primarily due to a reduction of insurance

costs and other expenses.

During 2023 the Company received $2.6 million related to litigation with an insurer.

The net loss for 2024 was $17.5 million, or $1.72 per share, compared with the net loss for 2023 of $18.0 million, or $1.87 per share. For 2024 the year over-year-net loss was reduced by $3.1 million exclusive of the $2.6 million received in 2023 noted above.

Cocrystal reported unrestricted cash as of December 31, 2024 of $9.9 million, compared with $26.4 million as of December 31, 2023. Net cash used in operating activities for 2024 was $16.5 million, compared with $14.7 million for 2023. The Company had working capital of $9.2 million and 10.2 million common shares outstanding as of December 31, 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. 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 product 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 2025, our plans regarding further clinical development of such product candidates, and the viability and efficacy of potential treatments for diseases our product candidates are designed to treat, and expectations for the markets for certain therapeutics. 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 our need for additional capital to fund our operations over the next 12 months, inflation, the possibility of a recession, interest rate increases, imposed and threated tariffs, and geopolitical conflicts including those 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 including any adverse impacts on our ability to obtain raw materials for and otherwise 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 progress and results of the studies for CC-42344 and CDI-988 including the delay of the Phase 2a study for CC-42344 which may require us to incur substantial additional costs, the ability of us and our CROs to recruit volunteers for, and to otherwise 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 the biopharmaceutical and healthcare industry based on policies and actions taken by the Trump Administration in the U.S., the impact of the Trump Administration's policies and actions on regulation affecting the FDA and other healthcare agencies and potential staffing issues resulting therefrom, potential mutations in a virus we are targeting that may result in variants that are resistant to a product candidate we develop, and the potential for the development of effective treatments by competitors which could reduce or eliminate a prospective future market share commercializing any product candidates we may develop in the future. Further information on our risk factors is contained in our filings with the SEC, including the "Risk Factors" in Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2024. 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)

	December 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash	$ 9,860	$ 26,353
Restricted cash	75	75
Tax credit receivable	1,215	890
Prepaid expenses and other current assets	430	1,773
Total current assets	11,580	29,091
Property and equipment, net	153	271
Deposits	29	46
Operating lease right-of-use assets, net (including $152 and $42 to related party)	1,694	1,851
Total assets	$ 13,456	$ 31,259
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 2,127	$ 3,022
Current maturities of operating lease liabilities (including $49 and $42 to related party)	301	240
Total current liabilities	2,428	3,262
Long-term liabilities:		
Operating lease liabilities (including $104 and $0 to related party)	1,505	1,613
Total long-term liabilities	1,505	1,613

Total liabilities	3,933	4,875
Commitments and contingencies		
Stockholders' equity:		
Common stock $0.001 par value; 100,000 and 150,000 shares authorized as of December 31, 2024 and 2023, respectively; 10,174 shares issued and outstanding as of December 31, 2024 and 2023, respectively	10	10
Additional paid-in capital	342,931	342,288
Accumulated deficit	(333,418)	(315,914)
Total stockholders' equity	9,523	26,384
Total liabilities and stockholders' equity	$ 13,456	$ 31,259

COCRYSTAL PHARMA, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(unaudited)
(in thousands, except per share data)

	December 31,	
	2024	2023
Operating expenses:		
Research and development	$ 12,537	$ 15,169
General and administrative	5,341	5,990
Legal settlement	-	(2,600)
Total operating expenses	17,878	18,559
Loss from operations	(17,878)	(18,559)
Other income (expense):		
Interest income, net	537	640
Foreign exchange loss	(163)	(65)
Total other income, net	374	575
Net loss	$ (17,504)	$ (17,984)
Net loss per common share, basic and diluted	$ (1.72)	$ (1.87)
Weighted average number of common shares outstanding, basic and diluted	10,174	9,651

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Source: Cocrystal Pharma, Inc.