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Cocrystal Pharma Reports First Quarter 2025 Financial Results and Provides Updates on its Antiviral Drug-Development Programs

In vitro testing with CDI-988 demonstrated superior broad-spectrum antiviral activity against major norovirus variants

BOTHELL, Wash., May 15, 2025 (GLOBE NEWSWIRE) -- [Cocrystal Pharma, Inc.](#) (Nasdaq: COCP) ("Cocrystal" or the "Company") reports financial results for the three months ended March 31, 2025, and provides updates on its antiviral product pipeline, upcoming milestones and business activities.

"Our oral pan-viral protease inhibitor *CDI-988* is a potential breakthrough first-in-class treatment and prophylaxis for norovirus, a debilitating gastrointestinal infection that strikes millions globally each year," said Sam Lee, Ph.D., President and co-CEO of Cocrystal. "By precisely targeting the virus' core replication machinery, we believe *CDI-988* effectively combats all major strains of this highly contagious pathogen with exceptional *in vitro* activity demonstrated against the current circulating GII.17 and GII.4 strains. We're preparing to launch a U.S. human challenge study in the coming months – a critical step in advancing this transformative therapy to patients worldwide.

"Our novel, broad-spectrum drug candidates have the potential to fundamentally transform how we fight viral threats worldwide," said James Martin, CFO and co-CEO of Cocrystal. "We're advancing development of these assets for multibillion-dollar markets while remaining committed to a capital-efficient business model to maximize shareholder value."

Antiviral Product Pipeline Overview

We harness our revolutionary structure-based drug discovery platform technology to engineer next-generation, broad-spectrum antivirals that precisely disrupt viral replication mechanisms. Unlike traditional approaches, our platform technology identifies compounds that bind to highly conserved regions of viral enzymes, thereby creating a formidable defense against current viral threats as well as their mutations. By specifically targeting these evolutionary-constrained viral regions, our candidates maintain efficacy even as viruses mutate, while simultaneously minimizing off-target interactions that typically lead to adverse side effects. This dual advantage represents a significant breakthrough in antiviral drug development. Our innovative methodology fundamentally transforms the conventional drug discovery paradigm by eliminating the inefficient, resource-intensive cycles of high-throughput compound screening and prolonged hit-to-lead optimization. The result is faster identification of promising candidates with superior resistance profiles and safety characteristics.

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* 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 Phase 2a 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.
 - Dry powder inhalation formulation development and toxicology studies have been completed.
- *Influenza A/B program*
 - Our efforts to develop a preclinical lead of novel influenza replication inhibitors are ongoing.

Norovirus Program

Norovirus is a common and highly contagious virus that causes symptoms of acute gastroenteritis among people of all ages including nausea, vomiting, stomach pain and diarrhea as well as fatigue, fever and dehydration. Norovirus infection can be significantly more severe and prolonged in specific risk groups including infants, children, the elderly and people with immunodeficiency. Norovirus outbreaks occur most commonly in semi-closed communities and have become notorious for their occurrence in hospitals, nursing homes, childcare facilities, cruise ships, schools, disaster relief sites and military settings.

[In the U.S. alone, noroviruses are responsible for an estimated 21 million cases annually, including 109,000 hospitalizations, 465,000 emergency department visits and an estimated](#)

[900 deaths](#). The annual burden of norovirus to the U.S. is estimated at [\\$10.6 billion](#). Noroviruses are responsible for [up to 1.1 million hospitalizations and 218,000 deaths annually in children in the developing world](#). There is currently no effective treatment or effective vaccine for norovirus, and the ability to curtail outbreaks is limited.

- *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 subjects.
 - 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 high-dose cohort.
 - In April 2025 we announced that *CDI-988* showed superior broad-spectrum antiviral activity against GII.17 strains, the most prevalent strain in the U.S. and European countries in 2024-2025.
 - We expect to report topline oral *CDI-988* Phase 1 results from the high-dose healthy subject cohort in the second quarter of 2025.
 - We plan to initiate a human challenge study in the U.S. in the coming months to evaluate *CDI-988* as a norovirus treatment and prophylaxis.

SARS-CoV-2 and Other Coronavirus Program

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 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 high-

dose cohort.

- We expect to report topline oral *CDI-988* Phase 1 results from the high-dose healthy subject cohort in the second quarter of 2025.

First Quarter Financial Results

Research and development (R&D) expenses for the first quarter of 2025 were \$1.4 million, compared with \$3.0 million for the first quarter of 2024, with the decrease primarily due to a reduction in personnel costs and the timing of clinical study costs. General and administrative (G&A) expenses for the first three months of 2025 were \$1.0 million, compared with \$1.2 million for the first three months of 2024, with the decrease primarily due to a reduction in insurance costs and other expenses.

Net loss for the first quarter of 2025 was \$2.3 million, or \$0.23 per share, compared with net loss for the first quarter of 2024 of \$4.0 million, or \$0.39 per share.

Cocrystal reported unrestricted cash as of March 31, 2025 of \$6.9 million, compared with \$9.9 million as of December 31, 2024. Net cash used in operating activities for the first quarter of 2025 was \$2.9 million, compared with \$4.5 million for the first quarter of 2024. The Company had working capital of \$6.9 million and 10.2 million common shares outstanding as of March 31, 2025.

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 including the potential of our norovirus product candidate, our plans to initiate a human challenge study for our norovirus product candidate, and our plans with regard to initiating a second human challenge study for CC-42344. 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 threatened 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, 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, and our ability to meet our future liquidity needs. 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)

	March 31, 2025 (unaudited)	December 31, 2024
Assets		
Current assets:		
Cash	\$ 6,921	\$ 9,860
Restricted cash	75	75
Tax credit receivable	1,445	1,215
Prepaid expenses and other current assets	385	430
Total current assets	8,826	11,580
Property and equipment, net	127	153
Deposits	86	29
Operating lease right-of-use assets, net (including \$140 and \$152 to related party)	1,620	1,694
Total assets	<u>\$ 10,659</u>	<u>\$ 13,456</u>

Liabilities and stockholders' equity

Current liabilities:

Accounts payable and accrued expenses	\$ 1,622	\$ 2,127
Current maturities of operating lease liabilities (including \$51 and \$49 to related party)	309	301
Total current liabilities	<u>1,931</u>	<u>2,428</u>

Long-term liabilities:

Operating lease liabilities (including \$90 and \$104 to related party)	<u>1,424</u>	<u>1,505</u>
Total long-term liabilities	<u>1,424</u>	<u>1,505</u>
Total liabilities	<u>3,355</u>	<u>3,933</u>

Commitments and contingencies

Stockholders' equity:

Common stock, \$0.001 a par value: 100,000 shares authorized as of March 31, 2025 and December 31, 2024; 10,174 shares issued and outstanding as of March 31, 2025 and December 31, 2024

	10	10
Additional paid-in capital	343,013	342,931
Accumulated deficit	<u>(335,719)</u>	<u>(333,418)</u>
Total stockholders' equity	<u>7,304</u>	<u>9,523</u>
Total liabilities and stockholders' equity	<u>\$ 10,659</u>	<u>\$ 13,456</u>

COCRYSTAL PHARMA, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

(unaudited)

(in thousands, except per share data)

	Three months ended March 31,	
	2025	2024
Operating expenses:		
Research and development	1,360	2,950
General and administrative	981	1,208
Total operating expenses	<u>2,341</u>	<u>4,158</u>
Loss from operations	<u>(2,341)</u>	<u>(4,158)</u>
Other income (expense):		
Interest income (expense), net	37	220
Foreign exchange gain (loss), net	3	(18)
Total other income (expense), net	<u>40</u>	<u>202</u>
Net loss	<u>\$ (2,301)</u>	<u>\$ (3,956)</u>
Net loss per common share, basic and diluted	<u>\$ (0.23)</u>	<u>\$ (0.39)</u>
Weighted average number of common shares, basic and diluted	<u>10,174</u>	<u>10,174</u>

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Source: Cocrystal Pharma, Inc.