

May 13, 2024



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

- *Topline single ascending dose (SAD) Phase 1 results of oral CDI-988, the first potential pan-coronavirus-pan-norovirus oral antiviral, expected in the second quarter of 2024*
- *Enrollment completed in Phase 2a influenza A human challenge study of oral CC-42344, with topline results expected in the second half of 2024*
- *FDA pre-IND feedback for oral CC-42344 received in first quarter of 2024 provides better clarity on late-stage trial design*
- *Initiation of Phase 1 study of inhaled CC-42344, a potential influenza treatment and post-exposure prophylactic, planned for the second half of 2024*

BOTHELL, Wash., May 13, 2024 (GLOBE NEWSWIRE) -- [Cocrystal Pharma, Inc.](#) (Nasdaq: COCP) ("Cocrystal" or the "Company") reports financial results for the three months ended March 31, 2024, and provides updates on its antiviral product pipeline, upcoming milestones and business activities.

"The coming months promise to be exceptionally eventful with major inflection points in our dual norovirus-coronavirus and influenza programs expected this year," said Sam Lee, Ph.D., President and co-CEO of Cocrystal. "Among these, we expect topline results from the SAD portion of a first-in-human study with our pan-coronavirus and pan-norovirus oral protease inhibitor CDI-988, with the multiple ascending dose (MAD) portion of this study expected to begin in the second half of 2024.

"In our Phase 2a human challenge study with our novel broad-spectrum oral PB2 inhibitor CC-42344 for pandemic and seasonal influenza A, we expect to report topline results and to prepare an IND application to conduct a late-stage clinical study in the U.S. in the second half of 2024," Dr Lee added. "Also in our influenza program, preparations are underway to initiate a Phase 1 study in healthy volunteers with inhaled CC-42344 as a potential prophylactic and therapeutic for influenza A in the second half of this year."

"We continue advancing our development programs in high-value indications through a cost-efficient business model," said James Martin, CFO and co-CEO of Cocrystal. "We anticipate significant milestones this year and expect our cash will be sufficient to fund operating activities beyond the next twelve months as we tightly manage our financial resources."

Antiviral Product Pipeline Overview

We apply our proprietary structure-based drug discovery platform technology for developing broad-spectrum antivirals that inhibit the 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 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 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.](#)

- *Oral CC-42344 for the treatment of pandemic and seasonal Influenza A infections*
 - Our novel PB2 inhibitor CC-42344 has shown excellent *in vitro* antiviral activity against pandemic and seasonal influenza A 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 SAD 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 April 2023 we received approval from UK MHRA for oral CC-42344 Phase 2a 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 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.
 - In May 2024 we completed enrollment in the Phase 2a human challenge study.
 - In the second half of 2024 we expect to report topline results from the Phase 2a human challenge study and to prepare an IND application to conduct a late-stage study in the U.S.
- *Inhaled CC-42344 for the treatment of pandemic and seasonal Influenza A infections*
 - GLP toxicology study 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 studies.
 - We expect to begin a Phase 1 study with inhaled CC-42344 in Australia in the second half of 2024.
- *Influenza A/B Program*
 - Preclinical lead development of novel influenza replication inhibitors 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 SARS-CoV-2 protease inhibitors showed potent *in vitro* pan-viral activity against common human coronaviruses, rhinoviruses, and respiratory enteroviruses, 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 Pan-viral Protease Inhibitor CDI-988 for the treatment of coronaviruses and noroviruses*
 - Our novel broad-spectrum protease inhibitor *CDI-988* is being evaluated as a potential oral treatment for coronaviruses and noroviruses. *CDI-988* exhibited superior *in vitro* potency against SARS-CoV-2 and noroviruses, and demonstrated a favorable safety profile and PK properties.
 - 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 to report SAD cohort topline results from the Phase 1 study with *CDI-988* in the second quarter of 2024.

Norovirus Program

Norovirus is a highly contagious infection and is the most common cause of acute gastroenteritis, accounting for [nearly 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. 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.

- *Oral Pan-viral Protease Inhibitor CDI-988 for the treatment of norovirus infection*
 - *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.
 - 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 dosing subjects in a first-in-human study in healthy volunteers in Australia with oral *CDI-988* that is expected to serve as a Phase 1 study for both indications.
 - We expect to report SAD cohort topline results from the Phase 1 study with *CDI-988* in the second quarter of 2024.

First Quarter Financial Results

Research and development (R&D) expenses for the first quarter of 2024 were \$3.0 million, compared with \$3.9 million for the first quarter of 2023. The decrease was primarily due to a reduction of clinical preparation expenses as the CC-42344 influenza product candidate moved into a Phase 2a clinical study and the CDI-988 dual norovirus-coronavirus product candidate moved into a Phase 1 clinical study. General and administrative (G&A) expenses for the first quarters of 2024 and 2023 remained consistent at \$1.2 million.

Interest income for the first quarter of 2024 was \$220,000 and was primarily related to interest earned on cash held in interest bearing bank accounts, with no comparable item for the first quarter of 2023. Foreign exchange loss for the first quarter of 2024 were \$18,000, compared with \$78,000 in the prior-year quarter, with such expenses for both quarters related to foreign currency exchange rate fluctuations.

The net loss for the first quarter of 2024 was \$4.0 million, or \$0.39 per share, compared with the net loss for the first quarter of 2023 of \$5.2 million, or \$0.64 per share.

Cocrystal reported unrestricted cash as of March 31, 2024 of \$21.8 million, compared with \$26.4 million as of December 31, 2023. Net cash used in operating activities for the first quarter of 2024 was \$4.5 million, compared with \$3.1 million for the first quarter of 2023. The Company had working capital of \$22.1 million and 10.2 million common shares outstanding as of March 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. 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, 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 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.

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Financial Tables to follow

COCRYSTAL PHARMA, INC.

CONSOLIDATED BALANCE SHEETS
(in thousands)

	March 31, 2024 (unaudited)	December 31, 2023
Assets		
Current assets:		
Cash	\$ 21,842	\$ 26,353
Restricted cash	75	75
	1,003	890
Tax credit receivable		
Prepaid expenses and other current assets	1,572	1,773

Total current assets	24,492	29,091
Property and equipment, net	244	271
Deposits	46	46
Operating lease right-of-use assets, net (including \$26 and \$42 to related party)	1,764	1,851
Total assets	\$ 26,546	\$ 31,259
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 2,139	\$ 3,022
Current maturities of operating lease liabilities (including \$26 and \$42 to related party)	240	240
Total current liabilities	2,379	3,262
Long-term liabilities:		
Operating lease liabilities (including \$0 and \$0 to related party)	1,582	1,613
Total long-term liabilities	1,582	1,613
Total liabilities	3,961	4,875
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.001 a par value: 150,000 shares authorized as of March 31, 2024, and December 31, 2023; 10,174 shares issued and outstanding as of March 31, 2024 and December 31, 2023	10	10
Additional paid-in capital	342,445	342,288
Accumulated deficit	(319,870)	(315,914)
Total stockholders' equity	22,585	26,384
Total liabilities and stockholders' equity	\$ 26,546	\$ 31,259

COCRYSTAL PHARMA, INC.

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

	Three months ended March 31,	
	2024	2023
Operating expenses:		
Research and development	2,950	3,907
General and administrative	1,208	1,204
Total operating expenses	4,158	5,111
Loss from operations	(4,158)	(5,111)
Other income (expense):		
Interest income (expense), net	220	-
Foreign exchange loss	(18)	(78)
Total other income (expense), net	202	(78)
Net loss	\$ (3,956)	\$ (5,189)
Net loss per common share, basic and diluted	\$ (0.39)	\$ (0.64)
Weighted average number of common shares, basic and diluted	10,174	8,143

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Source: Cocrystal Pharma, Inc.