August 14, 2023

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

- *On track to begin a Phase 2a trial in the second half of 2023 with CC-42344 for the treatment of pandemic and seasonal influenza A*
- *Selected the novel protease inhibitor CDI-988 as development lead in the oral norovirus program*
- *CDI-988, the first potential dual coronavirus-norovirus oral antiviral, was cleared by the Australian regulatory agency for evaluation in healthy volunteers*

BOTHELL, Wash., Aug. 14, 2023 (GLOBE NEWSWIRE) -- Cocrystal Pharma, Inc. (Nasdaq: COCP) (Cocrystal or the Company) reports financial results for the three and six months ended June 30, 2023, and provides updates on its antiviral pipeline, upcoming milestones and business activities.

“This is an eventful time for Cocrystal with notable advancements in developing our pipeline of highly promising antivirals,” said Sam Lee, Ph.D., President and co-CEO of Cocrystal. “With our novel oral PB2 inhibitor *CC-42344* for the treatment of pandemic and seasonal influenza A, we are building on the favorable data from our Phase 1 trial with the submission of an application for UK MHRA (Medicine and Healthcare Products Regulatory Agency) approval to begin a Phase 2a human challenge trial later this year.

“In our COVID-19 program, we received approval from the Australian regulatory agency in late May to begin a first-in-human trial with our novel, broad-spectrum oral protease inhibitor *CDI-988*. Earlier this month we announced the selection of*CDI-988* as our lead oral norovirus candidate. This Phase I study is designed to access the safety, tolerability, and pharmacokinetics of *CDI-988* for both our COVID-19 and our norovirus programs. We expect to report top-line data of *CDI-988* Phase 1 study in 2024.”

“We have a number of significant near-term inflection points with our three leading antiviral programs including the commencement of multiple clinical trials,” said James Martin, CFO and co-CEO. “I’m pleased to report that under our cost-efficient business model, we believe our current cash position is sufficient to fund our planned operations for 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. It differs from traditional, empirical medicinal chemistry approaches that often require

iterative high-throughput compound screening and lengthy hit-to-lead processes. 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 both the virus and mutants of the virus, and also have reduced off-target interactions that may cause undesirable clinical side effects.

Influenza Programs

Influenza is a severe respiratory illness caused by the influenza A or B virus that results in disease outbreaks mainly during the winter months. The global seasonal influenza market including diagnostics, treatments and vaccines is projected to reach up to $27.95 billion by 2029, according to Data Bridge Market Research.

- *Pandemic and Seasonal Influenza A*
  - Our novel oral PB2 inhibitor *CC-42344* has shown excellent 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-controlled, dose-escalating Phase 1 trial to evaluate the safety, tolerability and pharmacokinetics (PK) of orally administered *CC-42344* in healthy adults.
  - In April 2022 we announced preliminary Phase 1 trial data demonstrating a favorable safety and PK profile in the first two cohorts in the single-ascending-dose portion of the study.
  - 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 *CC-42344* Phase 1 trial.
  - We entered into an agreement with a UK-based clinical research organization to conduct a Phase 2a human challenge study to evaluate safety, and viral and clinical measures of orally administered *CC-42344* in influenza A-infected subjects.
  - We submitted an application to the United Kingdom Medicines and Healthcare Products Regulatory Agency to conduct the Phase 2a human challenge study and, pending clearance, we expect to initiate the study in the second half of 2023.
  - Preclinical development is underway with an inhaled formulation of *CC-42344* as a potential treatment and prophylaxis for influenza A. We expect to complete active pharmaceutical ingredient (API) manufacturing in preparation for toxicity studies, and to begin the Phase 1 clinical trial in the first half of 2024.

- *Pandemic and Seasonal Influenza A/B Program*

  - In January 2019 we entered into an Exclusive License and Research Collaboration Agreement with Merck Sharp & Dohme Corp. (Merck) to discover and develop certain proprietary influenza antiviral agents that are effective against both influenza A and B strains. This agreement includes milestone payments of up to $156 million plus royalties on sales of products discovered under the agreement.
  - In January 2021 we announced completion of all research obligations under the

agreement, making Merck solely responsible for further preclinical and clinical development of these compounds.
    - In early 2023 Merck notified us of its intent to continue development of the proprietary compounds discovered under this agreement and of their filing on behalf of both companies of multiple U.S. and international patent applications associated with these compounds. Merck continues to be responsible for managing the patents.

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.

- *Oral Protease Inhibitor CDI-988*
    - In August 2023 we announced the selection of *CDI-988* as our lead candidate for development as a potential oral treatment for SARS-CoV-2. Designed and developed using our proprietary structure-based drug discovery platform technology, CDI-988 targets a highly conserved region in the active site of SARS-CoV-2 3CL (main) protease required for viral RNA replication.
    - *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 are supportive of once-daily dosing.
    - In May 2023 we announced approval of our application to the Australian regulatory agency for a planned randomized, double-blind, placebo-controlled Phase 1 trial in healthy volunteers.
    - We believe the FDA's guidance for further development of our antiviral candidate *CDI-45205* (described below) assists us in designing a subsequent Phase 2 trial for *CDI-988*.

- *Intranasal/Pulmonary Protease Inhibitor CDI-45205*

    - *CDI-45205* is our novel SARS-CoV-2 3CL (main) protease inhibitor and was among the broad-spectrum viral protease inhibitors we obtained from Kansas State University Research Foundation (KSURF) under an exclusive license agreement announced in April 2020. We believe the protease inhibitors obtained from KSURF have the ability to inhibit the inactive SARS-CoV-2 polymerase replication enzymes into an active form.
    - *CDI-45205* and several analogs showed potent *in vitro* activity against the main SARS-CoV-2 variants, surpassing the activity observed with the original Wuhan strain of the virus.
    - *CDI-45205* demonstrated good bioavailability in mouse and rat PK studies via intraperitoneal injection, and no cytotoxicity against a variety of human cell lines. *CDI-45205* also demonstrated a strong synergistic effect with the FDA-approved COVID-19 medicine remdesivir.

- In January 2022 we received guidance from the FDA regarding further preclinical and clinical development of *CDI-45205,* which provides a clearer pathway for future development.
- An IND-enabling study is ongoing with *CDI-45205*.

- *Replication Inhibitors*
  - We are using our proprietary structure-based drug discovery platform technology to discover replication inhibitors for orally administered therapeutic and prophylactic treatments for SARS-CoV-2. Replication inhibitors hold potential to work with protease inhibitors in combination therapy regimens.

Norovirus Program

- In August 2023 we announced our selection of the novel broad-spectrum 3CL protease inhibitor CDI-988 as our lead potential oral treatment for norovirus. *CDI-988* is approved for evaluation in a first-in-human trial in healthy volunteers in Australia, and that trial is expected to serve as the Phase 1 trial for both our norovirus and our coronavirus programs.
- With no approved treatments or vaccines, norovirus represents a significant unmet medical need. It 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.

Hepatitis C Program

- We are seeking a partner to advance development of*CC-31244* following the successful completion of a Phase 2a trial. This compound has shown favorable safety and preliminary efficacy in a triple-regimen Phase 2a trial in combination with Epclusa (sofosbuvir/velpatasvir) for the ultra-short duration treatment of individuals infected with the hepatitis C virus (HCV).
- HCV is a viral infection of the liver that causes both acute and chronic infection. The World Health Organization estimated that 58 million people worldwide had chronic HCV infection in 2019.

Corporate Updates

- In April we announced the appointment of Fred Hassan to our Board of Directors. Mr. Hassan's distinguished 40-year career includes serving in senior executive and director positions at global pharmaceutical companies and leading investment firms. He currently is Chairman of the investment firm Caret Group and a Director of Warburg Pincus LLC, a global private equity firm.
- In April we completed a $4.0 million private placement offering of common stock with Mr. Hassan and Phillip Frost, M.D., a Company co-founder and director, who currently is Chairman and CEO of OPKO Health.

Second Quarter Financial Results

Research and development (R&D) expenses for the second quarter of 2023 were $2.8

million, compared with $2.4 million for the second quarter of 2022. The increase was primarily due to preparations for a Phase 2a clinical trial with *CC-42344* for pandemic and seasonal influenza A, and preparations for advancing CDI-988's COVID-19 and norovirus programs toward a Phase 1 clinical trial.

General and administrative (G&A) expenses for the second quarter of 2023 were $1.5 million, compared with $1.4 million for the second quarter of 2022, with the increase primarily due to professional fees and general corporate cost increases.

The net loss for the second quarter of 2023 was $4.2 million, or $0.41 per share, compared with the net loss for the second quarter of 2022 of $24.4 million, or $3.00 per share. The second quarter of 2022 included a legal settlement of $1.6 million, which was returned to the Company in the third quarter of 2023 following a successful appeal of the trial court's summary judgment ruling. In the second quarter of 2022, the Company also recorded a non-cash goodwill impairment of $19.1 million.

Six Month Financial Results

R&D expenses for the six months ended June 30, 2023 were $6.7 million, compared with $5.2 million for the first six months of 2022. G&A expenses for the six months ended June 30, 2023 and 2022 were unchanged at $2.7 million.

During the first six months of 2022, the Company recorded a $19.1 million non-cash goodwill impairment. There was no comparable impairment charge during the first six months of 2023.

The net loss for the six months ended June 30, 2023 was $9.4 million, or $1.03 per share. The net loss for the six months ended June 30, 2022 was $28.6 million, or $3.48 per share, and reflected the litigation expense and non-cash impairment charge described above.

Cocrystal reported unrestricted cash as of June 30, 2023 of $32.4 million, compared with $37.1 million as of December 31, 2022. Net cash used in operating activities for the first six months of 2023 was $8.7 million. The Company had working capital of $34.1 million and 10.2 million common shares outstanding as of June 30, 2023. During the second quarter of 2023, the Company raised $4.0 million in a private placement offering of common stock that was priced "at-the-market" under Nasdaq Listing Rules.

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 2023 and beyond, the viability and efficacy of potential treatments for coronavirus and other diseases, 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 risks arising from interest rate increases in response to inflation, uncertainty in the financial markets, the possibility of a recession and the Ukraine war on our Company, our collaboration partners, and on the U.S., U.K., 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 and test animals as well as similar problems with our vendors and our current and any future CROs and contract manufacturing organizations (CMOs), the ability of our CROs to recruit volunteers for, and to proceed with, clinical studies, our reliance on Merck for further development in the influenza A/B program under the license and collaboration agreement, 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 trials, general risks arising from clinical trials, receipt of regulatory approvals, regulatory changes, 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 which may result in variants that are resistant to a product candidate we develop, and the outcome of the ongoing litigation with the insurance company. 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, 2022. 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)

	June 30, 2023	December 31, 2022
	(unaudited)	
Assets		
Current assets:		
Cash	$ 32,419	$ 37,144
Restricted cash	75	75
Tax credit receivable	1,207	716
Prepaid expenses and other current assets	1,200	2,243
Total current assets	34,901	40,178
Property and equipment, net	305	342
Deposits	46	46
Operating lease right-of-use assets, net (including $72 and $99 respectively, to related party)	167	274
Total assets	$ 35,419	$ 40,840
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 1,421	$ 976
Current maturities of finance lease liabilities	-	7
Current maturities of operating lease liabilities (including $62 and $59 respectively, to related party)	166	233
Total current liabilities	1,587	1,216
Long-term liabilities:		
Operating lease liabilities (including $10 and $42 respectively, to related party)	10	57
Total liabilities	1,597	1,273
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.001 par value; 150,000 shares authorized as of June 30, 2023, and December 31, 2022; 10,174 and 8,143 shares issued and outstanding as of June 30, 2023 and December 31, 2022	10	8
Additional paid-in capital	341,957	337,489
Accumulated deficit	(308,145)	(297,930)
Total stockholders' equity	33,822	39,567
Total liabilities and stockholders' equity	$ 35,419	$ 40,840

COCRYSTAL PHARMA, INC.

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

	Three months ended June 30,		Six months ended June 30,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	3,661	2,361	7,568	5,233
General and administrative	1,538	1,375	2,742	2,708
Legal settlement	-	1,600	-	1,600
Impairments	-	19,092	-	19,092
Total operating expenses	5,199	24,428	10,310	28,633
Loss from operations	(5,199)	(24,428)	(10,310)	(28,633)
Other income (expense):				
Interest income (expense), net	140	-	140	(1)
Foreign exchange loss	33	(1)	(45)	(14)
Change in fair value of derivative liabilities	-	1	-	12
Total other expense, net	173	-	95	(3)
Net loss	$ (5,026)	$ (24,428)	(10,215)	(28,636)
Net loss per common share, basic and diluted	$ (0.50)	$ (3.00)	(1.12)	(3.48)
Weighted average number of common shares outstanding, basic and diluted	10,065	8,143	9,109	8,143

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Source: Cocrystal Pharma, Inc.