November 14, 2022

Cocrystal Pharma Reports Third Quarter 2022 Financial Results and Provides Updates on its Antiviral Development Programs

- Completed enrollment in the Phase 1 study with novel, broad-spectrum antiviral PB2 candidate *CC-42344* for the treatment of pandemic and seasonal influenza A; remains on track to report topline results in 2022
- Announced oral presentation of *CC-42344* Phase 1 influenza A data at the World Antiviral Congress 2022 being held in December
- Selected novel antiviral candidate *CDI-988* for clinical development as an oral treatment for SARS-CoV-2 with Phase 1 study expected to begin in the first quarter of 2023

BOTHELL, Wash., Nov. 14, 2022 (GLOBE NEWSWIRE) -- Cocrystal Pharma, Inc. (Nasdaq: COCP) reports financial results for the three and nine months ended September 30, 2022, and provides updates on its antiviral pipeline, upcoming milestones and business activities.

“We are reporting continued progress in advancing our highly promising antiviral portfolio,” said Sam Lee, Ph.D., President and co-interim CEO of Cocrystal. “With enrollment completed in our *CC-42344* Phase 1 study for the treatment of pandemic and seasonal influenza A, we are on track to report topline safety and pharmacokinetic (PK) results later this year. The full trial results will be a key component of UK regulatory agency submission for our influenza A Phase 2a human challenge study. Subject to the agency’s review and clearance of our submission, we expect Phase 2a study initiation in the second half of 2023.

“We advanced our oral COVID-19 program with the selected the novel, broad-spectrum protease inhibitor *CDI-988* as our lead development candidate,” he added. “We are conducting IND-enabling toxicology studies with *CDI-988* and plan to file for regulatory clearance to begin a first-in-human trial in Australia in the first quarter of 2023. Preclinical development activities are ongoing in our norovirus program with plans to select a lead candidate in the first half of 2023.”

“The recent increase in patients hospitalized with viral disease particularly among the pediatric population underscores the need for effective, broad-spectrum antivirals and provides rationale for our approach in developing candidates with barriers to drug resistance,” said James Martin, CFO and co-interim CEO. “We continue to be well positioned to execute on our clinical and regulatory goals given our clean capital structure, cost-efficient business model and a cash balance we believe is sufficient to fund planned operations for the next three years. That said, we continue to pursue non-dilutive funding to further support development of our promising antiviral programs.”

Antiviral Product Pipeline Overview

Many commercial antiviral drugs are only effective against certain strains of a virus and are less effective or not effective at all against other strains or variants. Cocrystal is developing novel drug candidates that specifically target proteins involved in viral replication. Despite the numerous strains that may exist or emerge, these targeted enzymes are required for viral replication and are essentially similar (highly conserved) across all strains. By targeting these highly conserved regions of the replication enzymes, our antiviral compounds are designed to be effective against major virus strains.

COVID-19 and Other Coronavirus Programs
By targeting viral replication enzymes and protease, we believe it is possible to develop an effective treatment for all coronavirus diseases 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.

During 2022 Cocrystal entered into two agreements with the National Institute of Allergy and Infectious Diseases (NIAID) for exploratory preclinical studies to evaluate our 3CL protease inhibitors for the treatment of COVID-19. The NIAID collaboration announced in April 2022 for *in vitro* and *in vivo* studies evaluating the antiviral activity of our compounds has been successfully completed. In June 2022 we expanded our collaboration with the NIAID with a second agreement in which we provided our proprietary process chemistry information for oral 3CL protease inhibitors to the NIAID to support scale-up synthesis of a key intermediate of these compounds. This collaboration is ongoing.

- *Oral Protease Inhibitor CDI-988*
    - We selected *CDI-988* as our lead candidate for development as a potential oral treatment for SARS-CoV-2. *CDI-988*, which was designed and developed using our proprietary structure-based drug discovery platform technology, targets a highly conserved region in the active site of SARS-CoV-2 3CL (main) protease required for viral RNA replication.
    - *CDI-988* exhibits superior *in vitro* potency against SARS-CoV-2 with activity maintained against current variants of concern, and demonstrated a safety profile and PK properties that are supportive of daily dosing.
    - We are currently conducting good laboratory practice (GLP) toxicology studies in preparation for a Phase 1 study.
    - We plan to initiate a Phase 1 study in the first quarter of 2023. We believe the FDA's guidance for further development of our antiviral candidate *CDI-45205* (described below) provides us with a clearer pathway for our planned Phase 1 study with *CDI-988*, as well as directives for designing a subsequent Phase 2 study.

- *Intranasal/Pulmonary Protease Inhibitor CDI-45205*

    - An IND-enabling study is ongoing with *CDI-45205,* our novel SARS-CoV-2 3CL (main) protease inhibitor being developed as a potential treatment for COVID-19 and its variants.

- We received guidance from the FDA regarding further preclinical and clinical development of *CDI-45205* that provides a clearer pathway for future clinical development.
- *CDI-45205* and several analogs showed potent *in vitro* activity against the main SARS-CoV-2 variants to date including the Omicron variant, surpassing the activity observed with the original Wuhan strain.
- *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.
- *CDI-45205* 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.

- *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 a combination therapy regimen.

Influenza Programs

Influenza is a severe respiratory illness caused by either the influenza A or B virus that results in outbreaks of disease mainly during the winter months.

- *Pandemic and Seasonal Influenza A*
  - A novel PB2 inhibitor, *CC-42344* has shown excellent antiviral activity against influenza A strains including pandemic and seasonal strains, as well as strains resistant to Tamiflu® and Xofluza®. *CC-42344* also has favorable PK and drug-resistance profiles.
  - In March 2022 we initiated enrollment in our randomized, double-controlled, dose-escalating Phase 1 study to evaluate the safety, tolerability and pharmacokinetics of orally administered *CC-42344* in healthy adults.
  - In April 2022 we announced preliminary Phase 1 study data, demonstrating a favorable safety and PK profile in the first two cohorts administered single ascending doses of *CC-42344* at 100 mg and 200 mg.
  - In July 2022 we reported PK results from the single ascending dose of the study supporting once-daily dosing.
  - In November 2022 we announced the Phase 1 study had reached full enrollment and reiterated our expectation to report topline results in 2022.
  - We entered into an agreement with a UK-based clinical research organization to conduct a human challenge Phase 2a study evaluating safety, viral and clinical measures of orally administered *CC-42344* in influenza A-infected subjects. Under the human challenge model, healthy adults will be infected with the influenza A virus under carefully controlled conditions, which we believe will hasten trial enrollment and ensure subjects are infected with influenza A.
  - We expect to submit an application with the United Kingdom Medicines and Healthcare Products Regulatory Agency in early 2023 to conduct a human

challenge Phase 2a study. Pending clearance by the agency, we expect to initiate the study in the second half of 2023.

- *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. Merck is now solely responsible for further preclinical and clinical development of compounds discovered under this agreement, and continues development activities with the compounds discovered under this agreement.
  - In April 2022 Merck indicated it was continuing development of the compounds discovered under this agreement.

Norovirus Program

- We are developing certain proprietary broad-spectrum, non-nucleoside polymerases for the treatment of human norovirus infections using our proprietary structure-based drug design technology platform. We also hold exclusive rights to norovirus protease inhibitors for use in humans under the KSURF license.
- We are targeting the selection of a preclinical lead in the first half of 2023.
- Norovirus is a global public health problem responsible for nearly 90% of epidemic, non-bacterial outbreaks of gastroenteritis around the world.

Hepatitis C Program

- We are seeking a partner to advance the development of*CC-31244* following the successful completion of a Phase 2a study. This compound has shown favorable safety and preliminary efficacy in a triple-regimen Phase 2a study 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. In June 2022, the World Health Organization estimates that 58 million people worldwide have chronic HCV infections.

Third Quarter Financial Results

Research and development (R&D) expenses for the third quarter of 2022 were $3.9 million compared with $2.1 million for the third quarter of 2021, with the increase primarily due to the ongoing influenza A Phase 1 trial and advancement of the preclinical COVID-19 program. The Company anticipates higher R&D spending during the remainder of 2022 in preparation for additional clinical trials. General and administrative (G&A) expenses were $1.8 million for the third quarters of both 2022 and 2021.

The net loss for the third quarter of 2022 was $5.7 million, or $0.70 per share, compared with the net loss for the third quarter of 2021 of $3.9 million, or $0.48 per share.

Nine Month Financial Results

R&D expenses for the first nine months of 2022 were $9.1 million compared with $6.1 million for the first nine months of 2021. G&A expenses were $4.5 million for the first nine months of both 2022 and 2021.

The net loss for the first nine months of 2022 was $34.3 million, or $4.23 per share, and included the items described above. The net loss for the first nine months of 2021 was $10.5 million, or $1.44 per share.

Cocrystal reported unrestricted cash of $42.1 million as of September 30, 2022 compared with $58.7 million as of December 31, 2021. Net cash used in operating activities for the first nine months of 2022 was $16.5 million. The Company reported working capital of $43.3 million with 8.1 million common shares outstanding as of September 30, 2022.

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), hepatitis C viruses and noroviruses. 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 goals of initiating a Phase 1 study for our CDI-988 candidate in the first quarter of 2023, our expectations of reporting data from the Phase 1 clinical study of our CC-42344 candidate later in 2022 and timeline for filing with the UK regulatory agency and commencing a Phase 2a study in 2023, our plans to select a lead candidate for our norovirus program in the first half of 2023, the viability and efficacy of potential treatments for coronavirus and other diseases, expectations for the global market for therapeutics, our attempts to discover replication inhibitors, our ability to execute our clinical and regulatory goals, our expectations concerning R&D expenses, the expected sufficiency of our cash balance to fund our planned operations, our liquidity and our continued pursuit of non-dilutive funding. 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 arising from the impact of COVID-19 (including long-term and pervasive effects of the virus), inflation, interest rate increases and the Ukraine war on our Company, our collaboration partners, and on the national and global economy, including manufacturing and research delays arising from raw materials and labor shortages, supply chain disruptions and other business interruptions including and adverse impacts on our ability to obtain raw materials and test animals as well as similar problems with our vendors and our current Contract Research Organization (CRO) and any future CROs and

Contract Manufacturing Organizations, the results of the studies for CC-42344, 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 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 our appeal of the summary judgment. 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, 2021. 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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COCRYSTAL PHARMA, INC.

CONSOLIDATED BALANCE SHEETS
(in thousands)

	September 30, 2022 (unaudited)	December 31, 2021
Assets		
Current assets:		
Cash	$ 42,056	$ 58,705
Restricted cash	75	50
Prepaid expenses and other current assets	2,765	568
Total current assets	44,896	59,323
Property and equipment, net	378	453
Deposits	46	46
Operating lease right-of-use assets, net (including $113 and 153 respectively, to related party)	327	478
Goodwill	-	19,092
Total assets	$ 45,647	$ 79,392

Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 1,378	$ 1,297
Current maturities of finance lease liabilities	14	27
Current maturities of operating lease liabilities (including $57 and 53 respectively, to related party)	227	209
Derivative liabilities	-	12
Total current liabilities	1,619	1,545
Long-term liabilities:		
Finance lease liabilities	-	7
Operating lease liabilities (including $57 and 101 respectively, to related party)	119	291
Total long-term liabilities	119	298
Total liabilities	1,738	1,843
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.001 par value; 150,000 shares authorized as of September 30, 2022 and December 31, 2021; 8,143 shares issued and outstanding as of September 30, 2022 and December 31, 2021.	8	8
Additional paid-in capital	337,330	336,634
Accumulated deficit	(293,429)	(259,093)
Total stockholders' equity	43,909	77,549
Total liabilities and stockholders' equity	$ 45,647	$ 79,392

COCRYSTAL PHARMA, INC.

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

	Three months ended September 30,		Nine months ended September 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	3,872	2,105	9,105	6,061
General and administrative	1,822	1,848	4,530	4,458
Legal settlement	-	-	1,600	-
Impairments	-	-	19,092	-
Total operating expenses	5,694	3,953	34,327	10,519
Loss from operations	(5,694)	(3,953)	(34,327)	(10,519)
Other (expense) income:				
Interest expense, net	(1)	(1)	(2)	(4)
Foreign exchange loss	(5)	(4)	(19)	(4)
Change in fair value of derivative liabilities	-	17	12	27
Total other (expense) income, net	(6)	12	(9)	19
Net loss	$ (5,700)	$ (3,941)	(34,336)	(10,500)
Net loss per common share, basic and diluted	$ (0.70)	$ (0.48)	(4.23)	(1.44)
Weighted average number of common shares outstanding, basic and diluted	8,143	8,143	8,143	7,108

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Source: Cocrystal Pharma, Inc.