March 29, 2023

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

BOTHELL, Wash., March 29, 2023 (GLOBE NEWSWIRE) -- Cocrystal Pharma, Inc. (Nasdaq: COCP) reports financial results for the 12 months ended December 31, 2022, and provides updates on its antiviral pipeline, upcoming milestones and business activities.

“This is an eventful time for Cocrystal with multiple near-term milestones with our highly promising antiviral programs,” said Sam Lee, Ph.D., President and co-CEO of Cocrystal. “Preparations are ongoing with a UK regulatory filing to begin an influenza A Phase 2a human challenge study with our novel oral PB2 inhibitor *CC-42344*. Pending regulatory clearance, we expect patient enrollment to begin in the second half of this year.

“We are also preparing to file with the Australian regulatory agency to begin a first-in-human trial in our oral COVID-19 program with our novel, broad-spectrum protease inhibitor *CDI-988*. This trial is also slated to begin in the first half of 2023, subject to regulatory clearance,” he added. “In our norovirus program, preclinical development activities are ongoing and we plan to select a lead oral candidate by mid-2023.”

“We made significant progress over the past year that put us on pace to initiate two clinical trials during 2023,” said James Martin, CFO and co-CEO. “We expect our cash will be sufficient to fund operating activities for the coming year as we tightly manage our financial resources under our cost-efficient operating model. We also intend to pursue non-dilutive funding to further support development of our promising antiviral programs.”

Antiviral Product Pipeline Overview

We are developing antiviral therapeutics that inhibit the essential viral replication function of RNA viruses that cause acute and chronic viral 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. In designing drug candidates, we seek to anticipate and avert potential viral mutations leading to resistance. By designing and selecting drug candidates that interrupt the viral replication process and have specific binding characteristics, we seek to develop drugs that not only are effective against both the virus and possible mutants of the virus, but also have reduced off-target interactions that may cause undesirable clinical side effects. We will continue developing preclinical and clinical drug candidates using our proprietary drug discovery technology.

Influenza Programs

Influenza is a severe respiratory illness caused by either the influenza A or B virus that results in disease outbreaks mainly during the winter months. The global seasonal influenza market was valued at $6.5 billion in 2021 and 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 resistant to Tamiflu® and Xofluza®.
  - 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 pharmacokinetic (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 of the study supporting once-daily dosing.
  - In December 2022 we reported favorable safety and tolerability results from the Phase 1 study with *CC-42344* for influenza A.
  - We entered into an agreement with a UK-based clinical research organization to conduct a Phase 2a human challenge 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.
  - We expect to submit an application with the United Kingdom Medicines and Healthcare Products Regulatory Agency in the first half of 2023 to conduct this study. Pending clearance by the agency, 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 treatment and prophylaxis for influenza A.

- *Pandemic and Seasonal Influenza A/B Program*

  - Merck recently notified the Company that they continue development activities with the compounds discovered under this agreement and that they have filed on behalf of both companies multiple U.S. and international patent applications associated with these compounds. Merck continues to be responsible for managing the patents.
  - 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.

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.

- *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* exhibited 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.
  - Preparations are underway to submit an application to the Australian regulatory authority for a planned randomized, double-blind, placebo-controlled Phase 1 study. Pending regulatory clearance, we expect to initiate the study in the first half of 2023. We believe the FDA's guidance for further development of our antiviral candidate *CDI-45205* (described below) also 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 SARS-CoV-2 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.

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 an oral 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 infection.

2022 Financial Results

Research and development expenses for 2022 were $12.4 million compared with $8.8 million for 2021, with the increase primarily due to advancing our influenza lead candidate *CC-42344* through a Phase 1 trial and preparation for a Phase 2a clinical trial planned for 2023, as well as advancing our lead COVID-19 clinical oral candidate *CDI-988* in preparation for a Phase 1 clinical trial planned for 2023. General and administrative expenses for 2022 were $5.7 million compared with $5.4 million for 2021, with the increase primarily due to professional fees and litigation expenses.

The Company's litigation with an insurer resulted in the insurance company obtaining a summary judgment during the second quarter of 2022 and accounted for a potential $1.6 million adverse award. The Company filed an appeal in July 2022. Pending the outcome of the appeal, the Company paid $1.6 million into the registry of the court, which stayed execution of the judgment. The United States Court of Appeals for the Third Circuit held oral argument on the appeal on March 8, 2023, and the parties are still awaiting a ruling on the appeal.

The net loss for 2022 was $38.8 million, or $4.77 per share, compared with the net loss for 2021 of $14.2 million, or $0.16 per share. This increase was primarily due to a $19.1 million non-cash impairment-loss of goodwill and an increase in R&D expenses as we continue to advance CC-42344, CDI-988 and other product candidates.

Cocrystal reported unrestricted cash of $37.1 million as of December 31, 2022 compared with $58.7 million as of December 31, 2021. Net cash used in operating activities for 2022 was $21.4 million. The Company reported working capital of $39.0 million and 8.1 million common shares outstanding as of December 31, 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 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, 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 fund our planned operations, our liquidity and planned cost-efficient management of our financial resources, 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 and uncertainties 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 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 Contract Research Organization (CRO) and any future CROs and Contract Manufacturing Organizations, the results of the studies for CC-42344 and CDI-988, 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, 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)

	December 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash	$ 37,144	$ 58,705
Restricted cash	75	50
Tax credit receivable	716	-
Prepaid expenses and other current assets	2,243	568
Total current assets	40,178	59,323
Property and equipment, net	342	453
Deposits	46	46
Operating lease right-of-use assets, net (including $99 and $153 to related party)	274	478
Goodwill	-	19,092
Total assets	$ 40,840	$ 79,392
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 976	$ 1,297
Current maturities of finance lease liabilities	7	27
Current maturities of operating lease liabilities (including $59 and $53 to related party)	233	209
Derivative liabilities	-	12
Total current liabilities	1,216	1,545
Long-term liabilities:		

Finance lease liabilities	-	7
Operating lease liabilities (including $42 and $101 to related party)	57	291
Total long-term liabilities	57	298
Total liabilities	1,273	1,843
Commitments and contingencies		
Stockholders' equity:		
Common stock $0.001 par value; 150,000 shares authorized as of December 31, 2022 and December 31, 2021, respectively; 8,143 shares issued and outstanding as of December 31, 2022 and December 31, 2021, respectively	8	8
Additional paid-in capital	337,489	336,634
Accumulated deficit	(297,930)	(259,093)
Total stockholders' equity	39,567	77,549
Total liabilities and stockholders' equity	$ 40,840	$ 79,392

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

	December 31,	
	2022	2021
Operating expenses:		
Research and development	12,392	8,794
General and administrative	5,745	5,427
Legal settlement	1,600	-
Impairments	19,092	-
Total operating expenses	38,829	14,221
Loss from operations	(38,829)	(14,221)
Other (expense) income:		
Interest expense, net	(2)	(4)
Change in fair value of derivative liabilities	(18)	49
Foreign exchange loss	12	(9)
Total other income (expense), net	(8)	36
Net loss	$ (38,837)	$ (14,185)
Net loss per common share:		
Loss per share, basic and diluted	$ (4.77)	$ (0.16)
Weighted average number of common shares outstanding, basic and diluted	8,143	7,364

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Source: Cocrystal Pharma, Inc.