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Cocrystal Pharma Reports First Quarter 2021 Financial Results and Provides Business Update

BOTHELL, Wash., May 17, 2021 (GLOBE NEWSWIRE) -- [Cocrystal Pharma, Inc.](#) (Nasdaq: COCP) ("Cocrystal" or the "Company"), a clinical-stage biotechnology company discovering and developing novel antiviral therapeutics that target the replication machinery of influenza viruses, the SARS-CoV-2 virus, hepatitis C viruses and noroviruses, reports financial results for the three months ended March 31, 2021 and provides updates on its antiviral pipeline and business activities.

"We believe Cocrystal is well-positioned to advance the discovery and development of novel antiviral compounds to address major global medical concerns and create significant market opportunities for our company," said Gary Wilcox, Ph.D., Chairman and Chief Executive Officer of Cocrystal. "Following the successful financing completed earlier this month, we believe we have sufficient capital to fund our currently planned operations and product development programs through 2024."

"We remain on track to achieve key milestones this year with our coronavirus, norovirus and influenza A antiviral programs," said Sam Lee, Ph.D., President of Cocrystal. "As discussed in our [coronavirus update release](#) earlier this month, we continue developing novel SARS-CoV-2 oral protease inhibitors and are rapidly advancing lead compounds. We recently demonstrated strong *in vitro* synergistic effect between remdesivir and our protease inhibitor *CDI-45205* and are currently examining *in vitro* activity of our SARS-CoV-2 3CL protease inhibitors against emerging SARS-CoV-2 variants.

"We also expect to report initial proof-of-concept mouse-model read-out with our norovirus protease inhibitors next month," added Dr. Lee. "We believe that by targeting viral protease we may develop an effective treatment for norovirus gastroenteritis. This is a significant opportunity for Cocrystal given the lack of any effective antiviral treatment or vaccine for norovirus gastroenteritis, and the limited ability to curtail outbreaks of this highly contagious virus that causes symptoms of acute gastroenteritis.

"With our program for the treatment of seasonal and pandemic influenza, we are completing the remaining IND-enabling studies with *CC-42344* with preparations underway to initiate a Phase 1 study in the third quarter of this year. We look forward to providing additional details about this program including announcing our clinical strategy," Dr. Lee concluded.

Antiviral Development Pipeline Milestones and Updates

COVID-19 Programs

- In December 2020 we announced the selection of *CDI-45205* as the lead compound

for further development against coronaviruses including SARS-CoV-2, that causes COVID-19. *CDI-45205* was one of the broad-spectrum protease inhibitors that were obtained from Kansas State University Research Foundation (“KSURF”) under an exclusive license agreement announced in April 2020. That agreement provides Cocrystal with an exclusive, royalty-bearing license to develop and commercialize therapeutic, diagnostic and prophylactic products against coronaviruses, caliciviruses and picornaviruses based on antivirals discovered by KSURF. The Company believes the 3CL protease has the ability to convert the inactive SARS-CoV-2 replication enzymes into the active form. *CDI-45205* showed good bioavailability in mouse and rat pharmacokinetic studies via intraperitoneal injection, and also no cytotoxicity against a variety of human cell lines.

The Company recently demonstrated a strong *in vitro* synergistic effect with the FDA-approved COVID-19 medicine remdesivir. Additionally, a proof-of-concept animal study demonstrated that daily injection of *CDI-45205* exhibited favorable *in vivo* efficacy in MERS-CoV-2 infected mice. The Company has initiated scale-up synthesis and process chemistry development and is working toward pre-IND status with *CDI-45205*.

- Cocrystal has leveraged its antiviral development expertise by using its proprietary technology and drug discovery platform to launch two additional COVID-19 programs, novel SARS-CoV-2 3CL protease inhibitors and replication inhibitors. The Company anticipates identifying another SARS-CoV-2 preclinical 3CL lead for oral administration this year.

By targeting the viral replication enzymes and proteases, Cocrystal believes it is possible to develop effective treatments for all coronaviruses that cause COVID-19, Severe Acute Respiratory Syndrome (SARS) and Middle East Respiratory Syndrome (MERS).

Influenza A Program

- Completing IND-enabling activities with *CC-42344* with planned Phase 1 study initiation during the third quarter of 2021. *CC-42344* showed excellent antiviral activity against influenza A strains, including avian pandemic strains and Tamiflu-resistant strains, and has a favorable pharmacokinetic profile.

Influenza remains a major global concern. The World Health Organization (WHO) estimates approximately 1 billion cases of influenza annually worldwide, resulting in 3 million to 5 million cases of severe illness and 250,000 to 500,000 deaths. Approved influenza therapies have major limitations due to drug resistance and viral mutation. Cocrystal is designing influenza drug candidates to be active against drug-resistant strains, effective against future mutations and available through multiple routes of administration including oral, inhalation and injection.

Hepatitis C Program

- We have been seeking a partner to advance the development of *CC-31244* since completing Phase 2a trials. This compound showed favorable safety and preliminary efficacy in a triple regimen Phase 2a study in combination with Epclusa (sofosbuvir/velpatasvir) for the ultra-short treatment of individuals infected with the hepatitis C virus (HCV). To date, no other company has developed a short-duration

HCV treatment of 4 weeks or less with a high (>95%) sustained virologic response (SVR) at week 12.

HCV is a viral infection of the liver that causes both acute and chronic infection. According to the WHO, in 2017 HCV chronically affected an estimated 71 million people worldwide, including 3.5 million in the U.S. Approximately 399,000 people die each year from hepatitis C infection, mostly from cirrhosis and hepatocellular carcinoma.

Norovirus Program

- Completion of a proof-of-concept animal study is expected in the second quarter of 2021 with a broad-spectrum norovirus protease polymerase inhibitor. Cocystal is further developing certain proprietary broad-spectrum antiviral compounds to treat norovirus infections under its license agreement with KSURF.

Norovirus is a public health problem responsible for nearly 90% of epidemic, non-bacterial outbreaks of gastroenteritis around the world. Norovirus is a very common and highly contagious virus that causes symptoms of acute gastroenteritis including nausea, vomiting, stomach pain and diarrhea.

First Quarter 2021 and Recent Highlights

Licensing and Collaboration Agreements

- Completed all research obligations under the Merck exclusive worldwide license and collaboration agreement for influenza A/B antiviral compounds. As of mid-January 2021, Merck assumed all responsibility for further program development.
- Extended a drug discovery collaboration with HitGen and InterX, combining three independent platforms to discover and optimize molecules that may lead to novel antiviral drug candidates.

Research and Development

- Continued IND-enabling studies with influenza PB2 inhibitor *CC-42344* in preparation for initiating a Phase 1 clinical study in the third quarter of 2021.
- Developed scale-up synthesis of SARS-CoV-2 3CL protease inhibitor *CDI-45205*.
- Initiated SARS-CoV-2 3CL oral protease inhibitor program.
- Initiated SARS-CoV-2 replication inhibitor program.
- Continued proof-of-concept mouse norovirus model study with expected initial read-out in June 2021.

Scientific Presentation

- Presented an overview of Cocystal's drug discovery platform technology, including its unique ability to develop broad-spectrum antiviral therapeutics and its advantages compared with the traditional drug discovery and development process, at the "reimagine Health Research Symposium" in January 2021.

Financial Developments

- In May 2021, completed raise of \$36.4 million in net proceeds from a public offering of

common stock.

First Quarter Financial Results

Throughout 2020 Cocystal reported quarterly revenues under an influenza A/B collaboration with Merck consisting of research and development (R&D) services performed by Cocystal and reimbursed by Merck. In mid-January 2021 Merck assumed all activities and expenses associated with the continued development of the influenza A/B compounds discovered under this collaboration. As anticipated, Cocystal reported no revenues for the first quarter of 2021 compared with \$461,000 in revenues for the first quarter of 2020. Under the terms of the Merck collaboration, Cocystal is eligible to receive up to \$156 million in future payments related to designated development, regulatory and sales milestones, as well as royalties on product sales.

R&D expenses for the first quarter of 2021 were \$1.6 million compared with \$1.3 million for the first quarter of 2020, with the increase primarily related to increased spending on our COVID-19 and influenza programs. General and administrative expenses for the first quarter of 2021 were \$1.2 million versus \$1.1 million for the prior-year quarter, with the increase primarily due to insurance and professional fees.

The net loss for the first quarter of 2021 was \$2.7 million, or \$0.04 per share, compared with a net loss for the first quarter of 2020 of \$2.0 million, or \$0.05 per share.

The Company reported cash and cash equivalents of \$33.3 million as of March 31, 2021, compared with \$33.0 million as of December 31, 2020. The Company reported working capital of \$32.2 million as of March 31, 2021.

In May 2021, Cocystal closed an underwritten public offering of 26,000,000 shares of common stock at a price to the public of \$1.54 per share, and received net proceeds of approximately \$36.4 million less underwriting discounts and commissions.

About Cocystal Pharma, Inc.

Cocystal 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. Cocystal employs unique structure-based technologies and Nobel Prize-winning expertise to create first- and best-in-class antiviral drugs. For further information about Cocystal, please visit www.cocystalpharma.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 the expected future success of our discovery and development activities in addressing major global medical concerns, the expected achievement of key milestones in our antiviral programs and the anticipated timing of achieving such milestones, including reporting proof-of-concept mouse-model read-out with our norovirus protease inhibitors in June 2021, the planned initiation of the influenza A Phase 1 study during the third quarter of 2021, identifying another SARS-CoV-2 preclinical 3CL lead for oral administration in 2021, and our plans regarding the expected completion of a norovirus proof-of-concept animal study in the second quarter of 2021; our expectations and estimates regarding the future applications and effectiveness of,

and the market opportunities for, our product candidates; the expected results of Cocrystal's extended collaboration with HitGen and InterX; and future 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 arising from the impact of the COVID-19 pandemic on the national and global economy, on our collaboration partners and on our Company, including supply chain disruptions and our continued ability to proceed with our programs, our reliance on Merck for further development in the influenza A/B program under the license and collaboration agreement, HitGen's DNA Encoded Library technology and InterX's software performing as expected, the results of future preclinical and clinical studies, general risks arising from clinical trials, receipt of regulatory approvals, regulatory changes, and development of effective treatments and/or vaccines by competitors, including as part of the programs financed by the U.S. government. 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, 2020. 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.

Investor Contact:

LHA Investor Relations

Jody Cain

310-691-7100

jcain@lhai.com

COCRYSTAL PHARMA, INC.
CONSOLIDATED BALANCE SHEETS
(in thousands)

	March 31, 2021 (unaudited)	December 31, 2020
Assets		
Current assets:		
Cash	\$ 33,278	\$ 33,010
Restricted cash	50	50
Accounts receivable	-	556
Prepaid expenses and other current assets	363	399
Total current assets	33,691	34,015
Property and equipment, net	571	591
Deposits	46	46
Operating lease right-of-use assets, net (including \$25 and \$39 to related party)	451	498
Goodwill	19,092	19,092
Total assets	\$ 53,851	\$ 54,242
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 1,194	\$ 1,080

Current maturities of finance lease liabilities	36	39
Current maturities of operating lease liabilities (including \$25 and \$39 to related party)	167	178
Derivative liabilities	60	61
Total current liabilities	<u>1,457</u>	<u>1,358</u>
Long-term liabilities:		
Finance lease liabilities	28	34
Operating lease liabilities	308	345
Total long-term liabilities	<u>336</u>	<u>379</u>
Total liabilities	<u>1,793</u>	<u>1,737</u>
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.001 par value; 100,000 shares authorized as of March 31, 2021 and December 31, 2020; 71,469,000 and 70,439 shares issued and outstanding as of March 31, 2021 and December 31, 2020, respectively	72	71
Additional paid-in capital	299,632	297,342
Accumulated deficit	<u>(247,646)</u>	<u>(244,908)</u>
Total stockholders' equity	<u>52,058</u>	<u>52,505</u>
Total liabilities and stockholders' equity	<u>\$ 53,851</u>	<u>\$ 54,242</u>

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

	Three months ended March 31,	
	2021	2020
Revenues:		
Collaboration revenue	<u>\$ -</u>	<u>\$ 461</u>
Operating expenses:		
Research and development	1,577	1,283
General and administrative	1,161	1,139
Total operating expenses	<u>2,738</u>	<u>2,422</u>
Loss from operations	<u>(2,738)</u>	<u>(1,961)</u>
Other (expense) income:		
Interest expense, net	(1)	(2)
Change in fair value of derivative liabilities	1	(27)
Total other expense, net	<u>-</u>	<u>(29)</u>
Net loss	<u>\$ (2,738)</u>	<u>\$ (1,990)</u>
Net loss per common share, basic and diluted	<u>\$ (0.04)</u>	<u>\$ (0.05)</u>
Weighted average number of common shares outstanding, basic and diluted	71,248	41,662

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Source: Cocrystal Pharma, Inc.