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# Cocrystal Pharma Reports Second Quarter 2021 Financial Results and Provides Antiviral Program and Milestone Updates

- Influenza program Phase 1 clinical trial with *CC-42344* on track to begin in the third quarter of 2021
- COVID-19 program preclinical development with the novel oral SARS-CoV-2 protease inhibitors is advancing
- Two IND-enabling studies in the COVID-19 program expected to begin in the first half of 2022 prior to Phase 1 clinical trials
- \$67 million in cash at quarter-end is expected to fund current operations beyond 2024

BOTHELL, Wash., Aug. 16, 2021 (GLOBE NEWSWIRE) -- Cocrystal Pharma, Inc. (Nasdaq: COCP), ("Cocrystal" or the "Company"), a clinical-stage biotechnology company, reports financial results for the three and six months ended June 30, 2021, and provides updates on its antiviral pipeline, milestones and business activities.

"Our scientific team is rapidly advancing the discovery and development of novel antiviral compounds that are aimed at addressing unmet medical needs for antiviral therapeutics," said Sam Lee, Ph.D., President and co-interim CEO of Cocrystal. "Our novel antivirals are intended to halt the replication of viruses that cause serious human diseases.

"We plan to initiate IND-enabling studies in the first half of 2022 with our SARS-CoV-2 protease inhibitor, *CDI-45205*, for intranasal/pulmonary delivery, as well as with a novel oral SARS-CoV-2 protease inhibitor that we discovered with our proprietary structure-based drug discovery technology. Our plan is to hold a pre-IND meeting with the FDA with *CDI-45205* this year, followed by a pre-IND meeting with our novel oral inhibitor in the first half of 2022," he added. "We are encouraged by recent *in vitro* laboratory data indicating *CDI-45205* is highly active against the SARS-CoV-2 (Wuhan strain) as well as four variants of concern, including the Delta variant. We are also very excited by recent preclinical data with our SARS-CoV-2 oral inhibitors. We plan to initiate drug substance and drug product manufacturing with these oral inhibitors this year.

"We are on track this quarter to initiate a Phase 1 clinical trial in healthy volunteers with *CC-42344*, our lead compound being developed for the treatment of seasonal and pandemic influenza," Dr. Lee concluded.

"We are in a good financial position at the second quarter with more than \$67 million in cash and a clean balance sheet consisting of common stock only with no debt," said James Martin, CFO and Co-Interim CEO. "We believe our capital is sufficient to fund planned operations beyond 2024, including clinical trials, as we advance toward commercialization."

## Antiviral Pipeline Overview

## COVID-19 Programs

- By targeting viral replication enzymes and proteases, Cocrystal believes it is possible to develop effective treatments for all coronaviruses including SARS-CoV-2, SARS-CoV and MERS-CoV.
- *CDI-45205* was among the broad-spectrum viral protease inhibitors obtained from Kansas State University Research Foundation (KSURF) under an exclusive license agreement announced in 2020. Cocrystal entered into the KSURF agreements to enable the rapid advancement of COVID-19 programs.
- *CDI-45205* has demonstrated a strong *in vitro* synergistic effect with the FDA-approved COVID-19 medicine remdesivir.
- Proof-of-concept data demonstrated that daily injections of *CDI-45205* exhibited favorable *in vivo* efficacy in mice infected with MERS-CoV-2.

## Influenza A Program

- The Phase 1 clinical study with *CC-42344* is expected to be conducted in Australia, which offers favorable regulatory policies and a clinical trial environment that aligns with the Company's strategy for rapid, cost-efficient and high-quality clinical development.
- *CC-42344* showed broad-spectrum and potent antiviral activity against influenza A strains, including avian pandemic strains, Tamiflu- and Xofluza-resistant strains, along with a favorable pharmacokinetic profile.
- Influenza remains a major global concern. An influenza pandemic is a global outbreak of new influenza A virus. According to the World Health Organization (WHO) there are 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.

## Norovirus Program

- Cocrystal is 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.

## Hepatitis C Program

- Cocrystal is seeking a partner to advance the development of *CC-31244* following completion of a Phase 2a trial. This compound showed favorable safety and preliminary efficacy in a triple regimen Phase 2a study in combination with Eplusa (sofosbuvir/velpatasvir) for the ultra-short duration treatment of individuals infected with the hepatitis C virus (HCV). To date, no other company has developed an HCV treatment of 4 weeks or less with a high (>95%) sustained virologic response at Week 12.
- HCV is a viral infection of the liver that causes both acute and chronic infection. According to the WHO, in 2017 an estimated 71 million people worldwide had chronic HCV infection, 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.

## Second Quarter 2021 and Recent Corporate Highlights

- Designated President Dr. Lee and CFO Martin as Co-Interim CEOs, following the unexpected passing of Chairman, CEO and co-founder Dr. Gary Wilcox. Roger Kornberg, Ph.D., co-founder, Chief Scientist, Director and Chairman of the Scientific Advisory Board, was named Chairman of the Board, and Steve Rubin, Director of Cocrystal and its predecessor company since 2008, was named Vice Chairman.
- Raised \$36.4 million in net proceeds from a public offering of common stock in May 2021.
- Cocrystal common stock was added to the Russell Microcap<sup>®</sup> Index, a broadly used performance measure for smaller growth stocks in the U.S.

## **Second Quarter Financial Results**

Throughout 2020 Cocrystal reported quarterly revenues under an influenza A/B collaboration with Merck consisting of research and development (R&D) services performed by Cocrystal and reimbursed by Merck. In 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, Cocrystal reported no revenues for the second quarter of 2021 compared with \$554,000 in revenues for the second quarter of 2020. Under the terms of the Merck collaboration, Cocrystal is eligible to receive up to \$156 million in future payments related to designated developments, regulatory and sales milestones, as well as royalties on product sales.

R&D expenses for the second quarter of 2021 were \$2.7 million compared with \$2.0 million for the second quarter of 2020, with the increase primarily related to higher spending on the COVID-19 and influenza programs. The Company expects R&D expenses to increase in the second half of 2021 with the initiation of a clinical trial in the influenza A program and advancements with the COVID-19 programs toward clinical development. General and administrative (G&A) expenses for the second quarter of 2021 were \$1.1 million versus \$2.0 million for the prior-year quarter, with the decline primarily due to reduced professional fees.

The net loss for the second quarter of 2021 was \$3.8 million, or \$0.04 per share, compared with a net loss for the second quarter of 2020 of \$3.5 million, or \$0.07 per share.

## **Year to Date Financial Results**

The Company did not report revenues for the first six months of 2021 versus \$1.0 million for the first six months of 2020. The 2020 revenues were reimbursement for R&D services performed under the influenza A/B program with Merck. In January 2021, the influenza A/B program was advanced for continued development of the antiviral agents at Merck. Merck is responsible for funding continued development of the compounds.

R&D expenses for the first half of 2021 increased 33% to \$4.3 million and G&A expenses decreased 29% to \$2.2 million, both compared with the first six months of 2020. The increased R&D in 2021 was primarily due to development of COVID-19 programs and preparation to advance our influenza A program into clinical trials.

The net loss for the six months ended June 30, 2021 was \$6.6 million, or \$0.08 per share, compared with a net loss for the six months ended June 30, 2020 of \$5.5 million, or \$0.12 per share.

The Company reported cash and cash equivalents of \$67.1 million as of June 30, 2021 compared with \$33.0 million as of December 31, 2020. The Company reported working capital of \$65.0 million as of June 30, 2021.

### **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](http://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 the expected advancement of our antiviral programs, including the planned initiation of the influenza A Phase 1 study during the third quarter of 2021, the planned pre-IND meetings with the FDA and the expected initiation of two IND-enabling studies in the COVID-19 program in the first half of 2022 and subsequent Phase 1 clinical trials, the anticipated initiation of SARS-CoV-2 oral inhibitors manufacturing in 2021; our expectations and estimates regarding the future applications and effectiveness of, and the market opportunities for, our product candidates; our expectations related to conducting clinical trials in Australia; our expectations regarding future operating results; the expected results of Cocrystal's collaboration with Merck, including potential receipt of future milestone payments of up to \$156 million and royalties; ; 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, CROs, CMOs, and on our Company, including raw material and test animal shortages and other supply chain disruptions, the ability of our CROs to recruit volunteers for, and to proceed with, clinical trials, possible delays resulting from the lockdown in Australia, the cooperation of the FDA in accelerating development in our COVID-19 program, our reliance on Merck for further development in the influenza A/B program under the license and collaboration agreement, our collaboration partners' technology and software performing as expected, the results of future preclinical and clinical trials, 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.

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Financial Tables to follow

**COCRYSTAL PHARMA, INC.**

**CONSOLIDATED BALANCE SHEETS**  
(in thousands)

	June 30, 2021	December 31, 2020
	<u>(unaudited)</u>	
<b>Assets</b>		
Current assets:		
Cash	\$ 67,062	\$ 33,010
Restricted cash	50	50
Accounts receivable	-	556
Prepaid expenses and other current assets	225	399
Total current assets	<u>67,337</u>	<u>34,015</u>
Property and equipment, net	539	591
Deposits	46	46
Operating lease right-of-use assets, net (including \$10 to related party)	403	498
Goodwill	19,092	19,092
Total assets	<u>\$ 87,417</u>	<u>\$ 54,242</u>
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 2,138	\$ 1,080
Current maturities of finance lease liabilities	33	39
Current maturities of operating lease liabilities (including \$10 to related party)	157	178
Derivative liabilities	51	61
Total current liabilities	<u>2,379</u>	<u>1,358</u>
Long-term liabilities:		
Finance lease liabilities	21	34
Operating lease liabilities	269	345
Total long-term liabilities	<u>290</u>	<u>379</u>
Total liabilities	<u>2,669</u>	<u>1,737</u>
Commitments and contingencies		

Stockholders' equity:

Common stock, \$0.001 par value; 100,000 shares authorized as of June 30, 2021 and December 31, 2020, respectively; 97,469 and 70,439 shares issued and outstanding as of June 30, 2021 and December 31, 2020, respectively

	98	71
Additional paid-in capital	336,117	297,342
Accumulated deficit	<u>(251,467)</u>	<u>(244,908)</u>
Total stockholders' equity	<u>84,748</u>	<u>52,505</u>
Total liabilities and stockholders' equity	<u>\$ 87,417</u>	<u>\$ 54,242</u>

**COCRYSTAL PHARMA, INC.**

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

	Three months ended June 30,		Six months ended June 30,	
	2021	2020	2021	2020
Revenues:				
Collaboration revenue	\$ -	\$ 554	\$ -	\$ 1,015
	-	554	-	1,015
Operating expenses:				
Research and development	2,747	1,976	4,324	3,259
General and administrative	1,081	2,028	2,242	3,167
Total operating expenses	<u>3,828</u>	<u>4,004</u>	<u>6,566</u>	<u>6,426</u>
Loss from operations	<u>(3,828)</u>	<u>(3,450)</u>	<u>(6,566)</u>	<u>(5,411)</u>
Other income (expense):				
Interest expense, net	(2)	(2)	(3)	(4)
Change in fair value of derivative liabilities	9	(43)	10	(70)
Total other income (expense), net	<u>7</u>	<u>(45)</u>	<u>7</u>	<u>(74)</u>
Net loss	<u>\$ (3,821)</u>	<u>\$ (3,495)</u>	<u>\$ (6,559)</u>	<u>\$ (5,485)</u>
Net loss per common share, basic and diluted	\$ (0.04)	\$ (0.07)	(0.08)	(0.12)
Weighted average number of common shares outstanding, basic and diluted	87,069	52,141	79,116	46,930

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Source: Cocrystal Pharma, Inc.