

August 9, 2019



# Cocrystal Pharma Reports Second Quarter 2019 Financial Results and Provides Corporate Update

– Company continues to drive clinical and research programs forward to achieve multiple value-driving milestones–

– Business development initiative underway with active discussions ongoing to secure additional strategic partnerships across pipeline –

BOTHELL, WA, Aug. 09, 2019 (GLOBE NEWSWIRE) -- [Cocrystal Pharma, Inc.](#) (NASDAQ: COCP), ("Cocrystal" or the "Company"), a clinical stage biotechnology company discovering and developing novel antiviral therapeutics, announced today its financial results for the quarter ended June 30, 2019 and provided a corporate update.

"We remain focused on advancing our hepatitis C clinical development program as well as driving forward our earlier-stage influenza and norovirus programs," commented Dr. Gary Wilcox, Chairman and Chief Executive Officer of Cocrystal.

"We see opportunity for us to successfully leverage the potential depth, breadth and efficacy of our antiviral programs within the current environment of significant deal activity between leading biopharmaceutical/ pharma companies and biotech companies. In addition, there have been recent industry research and development collaborations and licensing agreements for platform technologies, and we continue to explore similar opportunities with our platform," added Dr. Wilcox.

## Clinical Programs Overview

### ***Influenza A/B Inhibitors and Influenza A***

#### *Influenza A/B Inhibitors*

The Company is currently engaged in an exclusive license and collaboration agreement with Merck Sharp & Dohme Corp. ("Merck") to discover and develop certain proprietary influenza A/B antiviral agents.

Under the terms of the agreement, Merck will fund all research and development for the program, including clinical development, and will be responsible for worldwide commercialization of any products derived from the collaboration. Cocrystal was paid a \$4 million upfront license fee and is eligible to receive payments related to designated development, regulatory and sales milestones with the potential to earn up to \$156 million, plus undisclosed royalties on product sales.

#### *Influenza A*

Cocrystal is developing novel, broad spectrum influenza antivirals that are specifically designed to be effective against all significant A strains of the influenza virus and to have a high barrier to resistance due to the way they target the virus's replication machinery. Cocrystal's uniquely developed molecules target the influenza polymerase, an essential replication enzyme with several highly essential regions common to multiple influenza strains, including pandemic strains.

CC-42344, the Company's lead molecule, binds to a highly conserved PB2 site of influenza polymerase complex and exhibits a novel mechanism of action which inhibits replication. CC-42344 has shown excellent antiviral activity against influenza A strains, including avian pandemic strains and Tamiflu® resistant strains, and shows a favorable pharmacokinetic and safety profile. CC-42344 is currently being evaluated in preclinical IND-enabling studies for the treatment of influenza.

#### *Expected Near-Term CC-42344 Clinical Program Milestones*

- Complete preclinical IND-enabling studies in Q1 2020.
- File a regulatory submission in Q4 2020.
- Initiate Phase 1 study evaluating CC-42344 for the treatment of influenza in Q4 2020.

### ***Pan-Genotypic Non-Nucleoside Inhibitor for the Ultra-short Treatment of Hepatitis C***

CC-31244 is an investigational, oral, broad-spectrum replication inhibitor called a non-nucleoside inhibitor (NNI). It has been designed and developed using the Company's proprietary structure-based drug discovery technology to have a high barrier to drug resistance and to be a highly potent, selective NNI that is active against all HCV genotypes (1-6) with low level cytotoxicity in multiple cell types.

#### *U.S. Phase 2a Study - University of Maryland*

In January 2019, the Company announced safety and preliminary efficacy data from its triple regimen, U.S. Phase 2a study evaluating CC-31244 and Epclusa (sofosbuvir/velpatasvir) for the ultra-short treatment of HCV infected individuals.

The U.S. Phase 2a study is an open-label study designed to evaluate the safety, tolerability, and preliminary efficacy of CC-31244 and Epclusa, an approved 12-week therapy for HCV developed by Gilead Sciences, Inc., in 12 subjects with treatment-naïve HCV genotype 1. Subjects received oral 400 mg of CC-31244 and Epclusa for 2 weeks. Following this, the subjects continued Epclusa treatment alone for another 4 weeks. All subjects completed the 6-week treatment regimen. The treatment was well tolerated with no study discontinuations due to adverse events. Eight of 12 subjects achieved the primary efficacy endpoint of sustained virologic response at 12 weeks after completion of treatment (SVR12). SVR12 is defined as undetectable virus in blood 12 weeks after completion of treatment and is considered a virologic cure.

For additional information about the U.S. Phase 2a study of CC-31244 for the treatment of viral hepatitis C, please visit [ClinicalTrials.gov](https://clinicaltrials.gov) and reference identifier NCT03501550.

#### *Hong Kong Phase 2a Study*

Patient enrollment has commenced in the Phase 2a study of CC-31244 in Hong Kong SAR, China. The Phase 2a open-label study is being conducted at the Humanity & Health Research Centre, Humanity and Health Medical Group, in Hong Kong and will evaluate the safety, tolerability and preliminary efficacy of Cocrystal's CC-31244 in combination with Sofosbuvir and Daclatasvir with or without a protease inhibitor, for the treatment of hepatitis C (HepC). Sixteen patients will be enrolled in the Phase 2a study. This trial differs from the University of Maryland Phase 2a trial Cocrystal is conducting in that the trial will include a protease inhibitor. Under the Clinical Trial Agreement, the Phase 2a study of CC-31244 for the treatment of HepC will be sponsored and conducted by the Humanity & Health Research Centre, Hong Kong under the guidance of George Lau, M.D., FRCP (Edin, Lond), FHKAM (Med), FHKCP, FAASLD, Founding Chairman of Humanity and Health Medical Group, Hong Kong. As part of the agreement, Cocrystal will provide CC-31244, its lead product in development for HepC. Cocrystal's CC-31244 is an investigational, oral, potent, broad-spectrum replication inhibitor called a non-nucleoside inhibitor (NNI). It has a high barrier to drug resistance designed and developed using the Company's proprietary structure-based drug discovery technology. It is active against HCV genotypes 1-6 with no significant cytotoxicity in multiple cell types at high concentrations.

#### *Expected Near-Term CC-31244 Clinical Program Milestones*

- Report interim safety results for Hong Kong Phase 2a study in Q4 2019.
- Complete patient enrollment in Hong Kong Phase 2a study and report topline results in Q1 2020.
- Advance discussions with potential strategic partners to secure development and commercialization licensing agreement.

#### **Summary of Financial Results for Q2 2019**

As of June 30, 2019, Cocrystal had approximately \$7,474,000 cash on hand. Based on management's current projections, the Company expects to have sufficient cash to fund operations through the first quarter of 2020.

The Company had revenues of approximately \$592,000 during the quarter ended June 30, 2019, compared to no revenue during the quarter ended June 30, 2018. Revenues all came from Cocrystal's collaboration with Merck in relation to its influenza A/B program.

Total research and development expenses were approximately \$1,091,000 for the quarter ended June 30, 2019, compared with \$1,119,000 for the quarter ended June 30, 2018. General and administrative expenses were \$1,051,000 for the quarter ended June 30, 2019, compared with \$1,013,000 for the quarter ended June 30, 2018.

The Company reported loss from operations of approximately \$1,550,000 for the quarter ended June 30, 2019, compared to a loss of approximately \$2,132,000 for the quarter ended June 30, 2018. The loss decrease of \$582,000 is primarily due to revenue received during the quarter ended June 30, 2019.

The Company reported net loss of approximately \$1,515,000 for the quarter ended June 30, 2019, compared to a net loss of approximately \$1,343,000 for the quarter ended June 30, 2018. The overall increase in net loss of \$172,000 is primarily due to non-cash changes in our derivative liabilities of approximately \$259,000 and income tax benefit of approximately \$554,000 during the quarter ended June 30, 2018.

### **About Cocystal Pharma, Inc.**

Cocystal Pharma, Inc. is a clinical stage biotechnology company discovering and developing novel antiviral therapeutics that target the replication machinery of influenza viruses, 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. The Company is developing CC-31244, an investigational, oral, broad-spectrum replication inhibitor called a non-nucleoside inhibitor (NNI). CC-31244 is currently being evaluated in a Phase 2a study for the treatment of hepatitis C as part of a cocktail for ultra-short therapy of 4 to 6 weeks. Cocystal recently entered into an exclusive worldwide license and collaboration agreement with Merck & Co., Inc. to discover and develop certain proprietary influenza A/B antiviral agents. CC-42344, the Company's molecule for the treatment of influenza A, is currently being evaluated in preclinical IND-enabling studies. In addition, the Company has a pipeline of promising early preclinical programs and continues to identify and develop non-nucleoside polymerase inhibitors for norovirus gastroenteritis using the Company's proprietary structure-based drug design technology platform. For further information about Cocystal, please visit [www.cocystalpharma.com](http://www.cocystalpharma.com).

### **Forward-Looking Statements**

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including anticipated advancements under our collaboration agreement with Merck, achievement of expected near-term clinical and research milestones, including the expected progress and timing of the influenza A IND-enabling studies and Phase 1 study, the hepatitis C Phase 2a study in Hong Kong, expected advancement of discussions with potential strategic partners, 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, risks arising from our reliance on continuing collaboration with Merck under the collaboration agreement, the availability of products manufactured by third parties, the results of preclinical and clinical studies, the research organizations' inability to recruit subjects and complete the studies timely or at all, including as the result of civil unrest and political instability in Hong Kong, general risks arising from clinical trials, receipt of regulatory approvals, our ability to find and enter into agreements with suitable collaboration partners, unanticipated litigation and other expenses and factors that affect the capital markets in general and early stage biotechnology companies specifically. 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, 2018. 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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