

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

 Following new positive data from Phase 2a study, Company outlines next steps in clinical development plan for lead program CC-31244 for ultrashort treatment of hepatitis C (HepC)

 Preclinical influenza A/B program fully-funded by development and commercialization partner, Merck Sharp & Dohme Corp. (Merck) advancing with lead molecule selection expected in Q4 2020 –

- Fully-owned influenza A program expected to commence Phase 1 clinical study in
  Q4 2020 –
- Management advancing business development discussions across pipeline –
- Company has sufficient capital to fund development programs and operations through the end of 2020 –

BOTHELL. WA. Nov. 12. 2019 (GLOBE NEWSWIRE) -- Cocrystal Pharma, (NASDAQ: COCP), ("Cocrystal" or the "Company"), clinical stage Inc. biotechnology company discovering and developing novel antiviral therapeutics, announced today its financial results for the guarter ended September 30, 2019 and provided a corporate update.

"2019 has been an active and very productive year for the Company. We continue to drive our clinical and research programs forward and believe we now have established a clear development pathway for our lead program CC-31244 for the ultrashort treatment of HepC," commented Dr. Gary Wilcox, Chairman and Chief Executive Officer of Cocrystal. "Over the past nine months, we have worked closely with the Merck team advancing the influenza A/B antiviral agents and have had monthly and quarterly collaborative discussions that are guiding the next phase of this important program. We are very encouraged by the scientific developments made to-date and expect the lead influenza A/B molecule to be selected in the fourth quarter of next year."

"On the corporate side, we expect to close the year with a strong financial position, having secured enough cash runway to fund operations through 2020. Additionally, we remain opportunistic as we advance our ongoing business development discussions with the goal of securing additional strategic partnerships across our pipeline in order to infuse non-dilutive

capital into the Company, as witnessed by our Merck transaction. As we move into 2020, we believe the Company is well positioned to successfully achieve the corporate and clinical milestones in front of us," added Dr. Wilcox.

#### **Programs Overview**

*Influenza A/B Inhibitors:* Exclusive license and collaboration agreement with Merck to discover and develop certain proprietary influenza A/B antiviral agents.

 Under the terms of the agreement, Merck is funding all research and development for the program, including clinical development, and will be responsible for worldwide commercialization of any products derived from the collaboration.

#### **Upcoming Influenza A/B Program Milestones**

 Lead influenza A/B molecule to advance into clinical study is expected to be selected in Q4 2020.

**CC-42344 Influenza Program**: 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' replication machinery.

- Lead molecule in development: 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 has synergistic effects with approved influenza antivirals, including Xofluza and Tamiflu.
- CC-42344 is currently being evaluated in preclinical IND-enabling studies for the treatment of influenza. Company expects to move into clinical development in 2020.

#### **Upcoming CC-42344 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.

### **CC-31244 HepC Clinical Program**: Pan-Genotypic Non-Nucleoside Inhibitor for Ultrashort Treatment

- Lead molecule: CC-31244, an investigational, oral, broad-spectrum replication inhibitor called a non-nucleoside inhibitor (NNI), currently in Phase 2 program.
- New positive data from U.S. Phase 2a study recently presented at the AASLD 2019 Liver Meeting:
  - Patients that achieved sustained virologic response (SVR) 12, which is considered a cure had significantly higher frequencies of terminally differentiated effector memory CD8+ T cells compared with those who relapsed, allowing identification of patients more likely to respond to ultrashort treatment.
- Planning additional toxicology study to extend CC-31244 safety profile.
- Planning Phase 2b study of CC-31244 with new data to target patients and include six

- weeks of CC-31244 along with six weeks treatment of Gilead's Epclusa.
- Enrollment in the investigator-sponsored Phase 2a study of CC-31244 in Hong Kong SAR, China being conducted at the Humanity & Health Research Centre, Humanity and Health Medical Group remains ongoing. The Phase 2a study in Hong Kong is designed to 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 HepC. The expected completion of enrollment has been delayed a quarter due, in part, to the civil unrest and political instability in Hong Kong.

#### **Upcoming CC-31244 Clinical Program Milestones:**

- Complete patient enrollment in investigator-sponsored Hong Kong Phase 2a study in Q1 2020.
- Commence Phase 2b enabling toxicology study in H2 2020.
- Advance discussions with potential strategic partners to secure development and commercialization licensing agreement.

For additional information about the U.S. Phase 2a study of CC-31244 for the treatment of viral hepatitis C, please visit <u>ClinicalTrials.gov</u> and reference identifier NCT03501550.

#### **Summary of Financial Results for the Quarter Ended September 30, 2019**

As of September 30, 2019, the Company had approximately \$6,044,000 cash on hand. On November 4, 2019, the Company closed a public offering and received gross proceeds of approximately \$3.0 million and net proceeds of \$2.6 million. Based on management's current projections, the Company expects to have sufficient cash to fund operations through the end of 2020.

The Company recorded revenue for the three and nine months ended September 30, 2019 of \$492,000 and \$6,162,000, respectively, compared to no revenue during the same periods ended September 30, 2018. Revenue resulted from the Merck Collaboration during the three months ended September 30, 2019 and consisted of program services and expense reimbursements received for research and development costs associated with the Company's influenza A/B program in accordance with the Merck Collaboration Agreement, and for the nine months ended September 30, 2019 of program services, expense reimbursements and an initial license payment.

Total research and development expenses for the three and nine months ended September 30, 2019 were approximately \$1,077,000 and \$3,046,000, respectively, compared with approximately \$1,467,000 and \$3,464,000 for the three and nine months ended September 30, 2018, respectively.

General and administrative expenses for the three and nine months ended September 30, 2019 were approximately \$1,223,000 and \$3,597,000, respectively, compared with \$952,000 and \$3,157,000 for the three and nine months ended September 30, 2018, respectively.

The Company reported net loss for the three and nine months ended September 30, 2019 of approximately \$1,780,000 and \$324,000, respectively, compared with a net loss of approximately \$1,868,000 and \$4,762,000 for the three and nine months ended September 30, 2018, respectively.

#### **About Cocrystal Pharma, Inc.**

Cocrystal 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. 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 anticipated advancements under our collaboration agreement with Merck, achievement of expected near-term clinical and research milestones, including the selection of the lead influenza A/B molecule, the expected progress and timing of the influenza A IND-enabling studies, filing of a regulatory submission and Phase 1 study, the anticipated progress and timing of the HepC 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 forwardlooking 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, litigation expenses 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, as updated and supplemented by the Quarterly Report on Form 10-Q for the quarter ended June 30, 2019. 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 and Media Contact:**

Jenene Thomas Communications, LLC (833) 475-8247 COCP@jtcir.com

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**COCRYSTAL PHARMA, INC.** 

## CONDENSED CONSOLIDATED BALANCE SHEETS (in thousands, except per share data)

		September 30, 2019 (unaudited)		December 31, 2018	
Assets	(	.aaaea,			
Current assets:					
Cash	\$	5,994	\$	2,723	
Restricted cash		50		29	
Accounts receivable		768		_	
Prepaid expenses and other current assets		201		191	
Total current assets		7,013		2,943	
Property and equipment, net		459		384	
Deposits		50		40	
Operating lease right-of-use assets, net		720		-	
Goodwill		65,195		65,195	
Total assets	\$	73,437	\$	68,562	
Liabilities and stockholders' equity					
Current liabilities:					
Accounts payable and accrued expenses	\$	1,690	\$	1,077	
Deferred rent		-		3	
Current maturities of finance lease liabilities		154		214	
Current maturities of operating lease liabilities		171		-	
Derivative liabilities		90		263	
Total current liabilities		2,105		1,557	
Long-term liabilities:					
Finance lease liabilities		18		117	
Operating lease liabilities		569		-	
Total long-term liabilities	_	587	_	117	
Total liabilities		2,692	_	1,674	
Commitments and contingencies					
Stockholders' equity:					
Common stock, \$.001 par value; 100,000 shares authorized as of September 30, 2019 and December 31,					
2018; 31,621 and 29,938 shares issued and outstanding as of September 30, 2019 and December 31,				22	
2018, respectively		32		30	
Additional paid-in capital		258,128		253,949	
Accumulated deficit		(187,415)	(	187,091)	
Total stockholders' equity	_	70,745	_	66,888	
Total liabilities and stockholders' equity	\$	73,437	\$	68,562	

See accompanying notes to condensed consolidated financial statements.

#### **COCRYSTAL PHARMA, INC.**

#### CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(unaudited)

(in thousands, except per share data)

Three months ended September 30,		Nine months ended September 30,		
	2019	2018	2019	2018

Revenues:				
Collaboration revenue	\$ 492	\$ -	\$ 6,162	\$ -
Total Revenues	492	_	6,162	
Operating expenses:				
Research and development	1,077	1,467	3,046	3,464
General and administrative	1,223	952	3,597	3,157
Total operating expenses	2,300	2,419	6,643	6,621
Loss from operations	(1,808)	(2,419)	(481)	(6,621)
Other (expense) income:				
Interest expense, net	(5)	-	(16)	(55)
Gain on settlement of mortgage note receivable	-	-	-	106
Loss on disposal of property and equipment	-	(61)	-	(61)
Change in fair value of derivative liabilities	33	129	173	410
Total other income, net	28	68	157	400
Loss before income taxes	(1,780)	(2,351)	(324)	(6,221)
Income tax benefit		483		1,459
Net loss	\$ (1,780)	\$ (1,868)	\$ (324)	\$ (4,762)
Net loss per common share: Loss per share, basic and diluted Weighted average number of common shares outstanding, basic and diluted	\$ (0.06) 31,621	\$ (0.06) 29,923	\$ (0.01) 31,201	\$ (0.17) 27,360

See accompanying notes to condensed consolidated financial statements.



Source: Cocrystal Pharma, Inc.