

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): March 9, 2021

Cocrystal Pharma, Inc.

(Exact name of registrant as specified in its charter)

<u>Delaware</u> (State or other Jurisdiction of Incorporation)	<u>001-38418</u> (Commission File Number)	<u>35-2528215</u> (IRS Employer Identification No.)
<u>19805 N. Creek Parkway Bothell, WA</u> (Address of principal executive offices)	<u>98011</u> (Zip Code)	

Registrant's telephone number, including area code: (786) 459-1831

(Former name or former address, if changed since last report.):

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Securities registered pursuant to Section 12(b) of the Act:

<u>Title of Each Class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
Common Stock	COCP	The Nasdaq Stock Market LLC (The Nasdaq Capital Market)

Item 7.01 Regulation FD Disclosure

Beginning at 7:00 a.m. ET on March 9, 2021, Cocrystal Pharma, Inc. (the "Company") is making available to the attendees of the virtual H.C. Wainwright Global Life Sciences Conference and the 33rd Annual Roth Conference a presentation by the Company's senior management. A copy of the presentation is being furnished as Exhibit 99.1 hereto and is incorporated herein by reference.

The information in this Item 7.01 (including Exhibit 99.1) shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities under such section, and shall not be deemed to be incorporated by reference into any filing of the Company under the Securities Act of 1933, or the Exchange Act.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

<u>Exhibit</u>	<u>Description</u>
99.1	<u>Cocrystal Pharma, Inc. Corporate Presentation, dated March 2021</u>

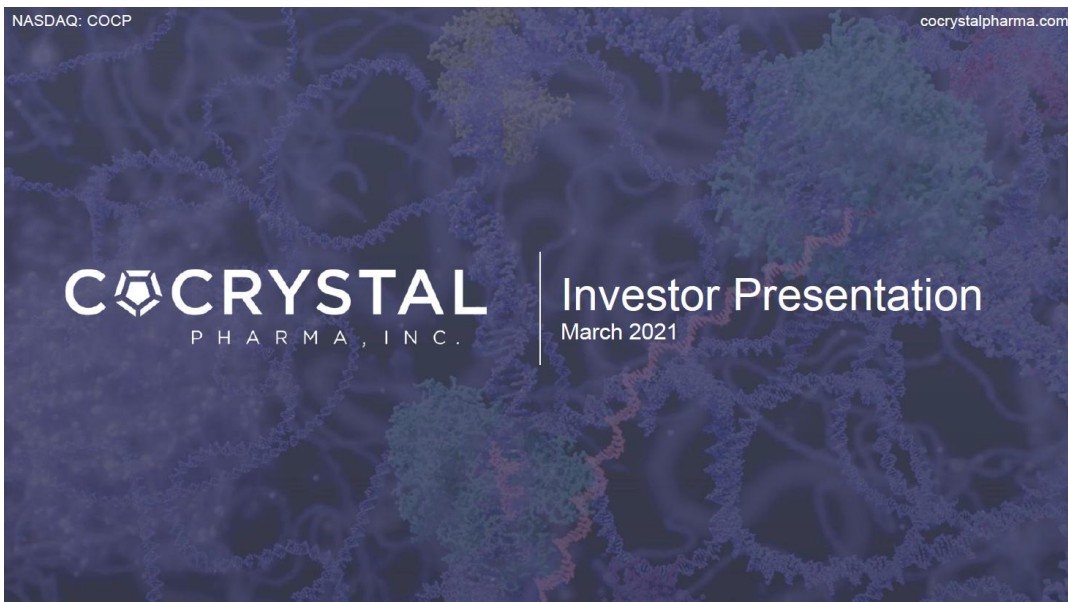
SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Cocrystal Pharma, Inc.

Date: March 9, 2021

By: /s/ James Martin
Name: James Martin
Title: Chief Financial Officer



Forward-Looking Statements

This presentation contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements regarding expected results of our collaboration with Merck Sharp & Dohme Corp. ("Merck"), including the anticipated characteristics of the drug candidates developed as the result of this collaboration, expected funding by Merck of future research, development and commercialization of products derived from such collaboration, and the expected future payments and royalties in connection with the collaboration; the expected progress in developing a compound for the effective treatment and prevention of COVID-19 infections and the anticipated timing of achieving the value-driving milestones, including achieving pre-IND status and development of additional COVID-19 inhibitors with novel mechanism of action in 2021; the expected progress of our Influenza A program, including the initiation of Phase 1 study in Q3 2021; the expected synergistic effects of CC-42344 with approved Influenza antivirals; the expected progress of our HCV program, including future partnership for further development; the expected progress of our norovirus program and the anticipated timing of achieving the value-driving milestones, including completion of a proof-of-concept animal study in H1 2021; and our estimates with respect to market opportunities and development pipeline. Forward-looking statements are prefaced by words such as "anticipate," "expect," "plan," "could," "may," "will," "should," "would," "intend," "seem," "potential," "appear," "continue," "future," "believe," "estimate," "forecast," "project," and similar words. Forward-looking statements are based on our current expectations and assumptions regarding our business, the economy and other future conditions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict. We caution you, therefore, against relying on any of these forward-looking statements. Our actual results may differ materially from those contemplated by the forward-looking statements for a variety of reasons, including, without limitation, the risks arising from the impact of the COVID-19 pandemic on our Company, including supply chain disruptions, our continued ability to proceed with our programs, receive necessary regulatory approvals and continue to rely on certain third parties, and on the national and global economy, risks arising from our reliance on continuing collaboration with Merck under the collaboration agreement, the future results of preclinical and clinical studies, general risks arising from clinical trials, receipt of regulatory approvals, development of effective treatments and/or vaccines by competitors, and our ability to find and enter into agreements with suitable collaboration partners. Further information on the risk factors that could cause actual results to differ materially from those expressed or implied by forward-looking statements, is contained in our filings with the Securities and Exchange Commission, including our Annual Report on Form 10-K for the year ended December 31, 2019, as amended and supplemented by the Quarterly Reports on Form 10-Q for the three months ended June 30, 2020 and the three months ended September 30, 2020. Any forward-looking statement made by us in this presentation 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.



About Cocrystal Pharma

Overview

Clinical-Stage Antiviral Company

Proprietary Drug Discovery Platform

Merck Collaboration

Potential For Prophylactic and Therapeutic Drugs

Target Diseases

Influenza

COVID-19

Hepatitis C

Norovirus Gastroenteritis



Investment Highlights

- Applying proprietary structure-based drug design technology to develop first- and best-in-class broad-spectrum antiviral drugs
- Large market opportunities for the treatment of acute and chronic viral diseases including seasonal and pandemic influenza, COVID-19, hepatitis C, and norovirus gastroenteritis
- Product candidates are tested for multiple routes of delivery
- Robust development pipeline including Merck collaboration
- Seasoned leadership includes two Nobel laureates and biotech veterans with proven success in drug discovery and development, business and finance
- Cost-efficient business model supported by strong cash position and clean capital structure

4

COCRYSTAL
PHARMA, INC.



Seasoned Leadership

Management Team

Gary Wilcox, Ph.D.

Chairman and Chief Executive Officer

- 35+ years of executive biotech leadership experience; played key role in Cialis development

**Sam Lee, Ph.D.**

President

- 25+ years of anti-infective drug discovery research experience; played key role in early development of phosphoinositide 3-kinase (PI3K) delta inhibitors

**James J. Martin, MBA, CPA**

Chief Financial Officer

- 25+ years of finance and management experience including providing financial leadership to commercial-stage, publicly traded health science companies



Scientific Advisory Board

Roger Kornberg, Ph.D.

Director, Chairman of the Scientific Advisory Board

- Professor
- Stanford University School of Medicine
- Nobel Laureate

Michael Levitt, Ph.D.

Member

- Professor
- Stanford University School of Medicine
- Nobel Laureate

Baek Kim, Ph.D.

Member

- Director of Center for Drug Discovery
- Emory University

Bob Lehman, Ph.D.

Member

- Professor (Emeritus)
- Stanford University School of Medicine

Gary Schoolnik, M.D.

Member

- Professor (Emeritus)
- Stanford University School of Medicine

Roland Strong, Ph.D.

Member

- Professor
- Fred Hutchinson Cancer Research Center

Christophe Verlinde, Ph.D.

Member

- Professor (Emeritus)
- University of Washington

5

COCRYSTAL
PHARMA, INC.

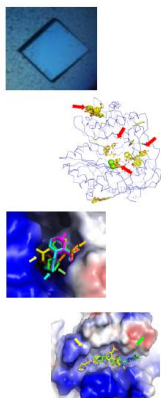


Proprietary Technology and Drug Discovery Platform

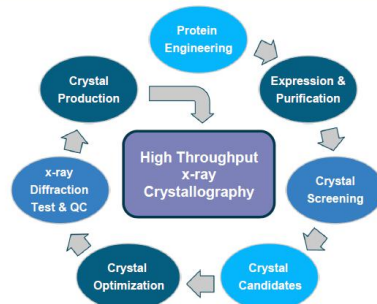
Technology Platform

Based on Nobel Prize-winning technology

- Near-atomic resolution
- X-ray quality crystal production
- Drug pocket selection
- Hit-to-lead process
- Lead optimization
- Drug candidates



Drug Discovery Platform




- Fully optimized operations from expression through high-resolution x-ray data
- Stringent quality oversight of procedures for crystal production
- High throughput x-ray data collection and computational methods
- Large-scale crystal production capabilities

6

COCRYSTAL
PHARMA, INC.



Robust Development Pipeline in High-Value Indications

Program		Discovery	Preclinical	Phase 1	Phase 2a	Phase 2b	Phase 3
Influenza A/B	Influenza A/B inhibitor	In collaboration with  MERCK					
Pandemic Influenza A	CC-42344 PB2 Inhibitor						
COVID-19 (Licensed from KSURF)	CDI-45205 Protease Inhibitor						
COVID-19	Replication Inhibitors						
Hepatitis C (HCV)	CC-31244 Pan-genotypic NS5B NNI						
Norovirus (Gastroenteritis)	Replication and Protease Inhibitors						

7

COCRYSTAL
PHARMA, INC.

Overview | Antiviral Program:
Influenza A/B Merck Collaboration

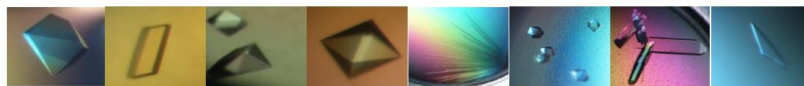
8



Influenza A/B Merck Collaboration



Influenza A/B Crystals



- Broad-spectrum, potent dual influenza A/B drug candidates
- Binds to highly conserved site of influenza A and B replication complex
- Expected to be active against seasonal, pandemic and existing drug-resistant influenza A and B strains

9

COCRYSTAL
PHARMA, INC.



Collaboration Terms Overview

Eligible to receive up to \$156 million in milestone payments
+ royalties on product sales

- Exclusive worldwide license and collaboration agreement to discover and develop proprietary influenza A/B antiviral agents signed in January 2019
- Agreement structure during the first 2 years:
 - Cocrystal and Merck jointly developed potent influenza A/B inhibitors
 - Cocrystal's R&D expenses reimbursed by Merck
 - Cocrystal met all research collaboration agreement obligations
- In the next phase, Merck is responsible for:
 - All funding and R&D, including clinical development
 - Worldwide commercialization of product(s) derived from collaboration

10

COCRYSTAL
PHARMA, INC.

Overview | Antiviral Program: COVID-19

11



Kansas State University Research Foundation Agreements

Cocrystal acquired exclusive patent rights and know-how for coronavirus and norovirus therapeutics for human use

- License agreements with KSURF in 2020 to further develop proprietary broad-spectrum compounds for coronavirus and norovirus
- Program status:
 - KSURF compounds demonstrated *in vitro* antiviral activity against SARS-Cov2 and *in vivo* efficacy in proof-of-concept animal model
 - Preclinical lead, CDI-45205, selected in Q4 2020 from KSURF licensed inhibitors
 - Compound to be developed for injectable and inhalation administration

12

COCRYSTAL
PHARMA, INC.



Status of COVID-19 Treatment

Cocrystal is researching and developing multiple options needed to prevent or treat COVID-19

There is no approved COVID-19 antiviral prophylactic treatment

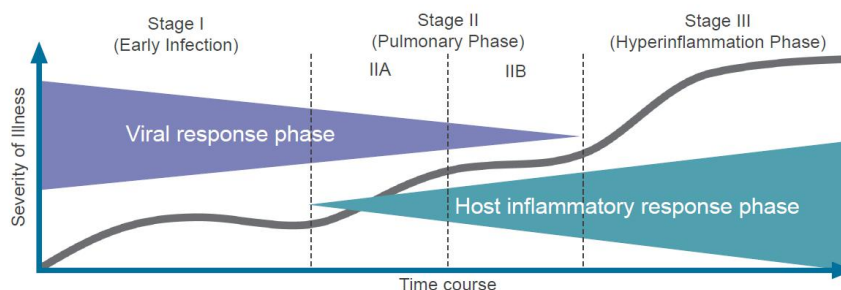
There is no effective COVID-19 antiviral therapeutic treatment

13

COCRYSTAL
PHARMA, INC.



Stages of COVID-19



Clinical Symptoms	Mild constitutional symptoms Fever >99.6°F Dry cough	Shortness of breath without (IIA) and hypoxia (IIB) (PaO ₂ /FIO ₂ ≤300 mmHg)	ARDS SIRS/shock Cardiac failure
Clinical Signs	Lymphopenia	Abnormal chest imaging Transaminitis Low-normal procalcitonin	Elevated inflammatory markers (CRP, LDH, IL-6, D-dimer, ferritin) Troponin, NT-proBNP elevation

14

COCRYSTAL
PHARMA, INC.



COVID-19 Program Status

- Potential to be effective treatment for COVID-19
- Develop SARS-CoV-2 inhibitors using proprietary platform technology
- Targeting viral replication complex and protease
- Potential first-in-class therapeutic *and* prophylactic treatment

Achieved Milestones and Next Steps:

- ✓ Q2 2020 Filed Additional Patent Application
- ✓ Q2 2020 Proof-of-Concept Animal Model Study
- ✓ Q2 2020 Initiated Preclinical Studies of COVID-19 Inhibitors
- ✓ Q3 2020 Identified Additional Inhibitors Using Cocrystal Proprietary Platform Technology
- ✓ Q4 2020 CDI-45205 Selected as Preclinical Lead from KSURF-licensed inhibitors
- 2021 Working toward pre-IND status with CDI-45205
- 2021 Develop additional COVID-19 Inhibitors with novel mechanism of action

15

COCRYSTAL
PHARMA, INC.

Overview | Antiviral Program:
Pandemic Influenza A

16



Significant Need for Pandemic Influenza Therapies

Seasonal and pandemic infections

1 Billion
cases annually²

3-5 Million
cases of severe
illness annually¹

Up to 650,000
deaths worldwide
annually¹

Current antiviral treatments are burdened by significant viral resistance

Approved influenza therapies have major limitations

- Tamiflu® has a long history of drug resistance issues³
- Xofluza™ (approved November 2018) has shown emergence of drug resistant mutations⁴

1. BCC Research (May 2018) The Global Influenza Market
2. Hussam, et al. Infection and Drug Resistance 2017;10:121-134
3. ScienceDaily (March 2014) Tamiflu-resistant influenza related to mutations in genome
4. NEJM Journal Watch (September 2018) A Promising Drug for Influenza?

17

COCRYSTAL
PHARM, INC.



Influenza Remains a Major U.S. and Global Concern

CNN Health • Food | Fitness | Wellness | Parenting | Vital Signs Live TV • U.S. Edition •

Flu season deaths top 80,000 last year, CDC says
September 27, 2018

KSL TV US on track for one of the worst flu seasons in decades Jan. 6, 2020

Science Swine flu strain with human pandemic potential increasingly found in pigs in China Jun. 29, 2020

WLRN Flu Season Off To Early Start, And It Could Be Severe Jan. 6, 2020

Medscape Flu Rates Rising, Pediatric Deaths Double Compared to 2018: CDC Dec. 30, 2019

the japan times Flu viruses resistant to new drug Xofluza uncovered in Japan NATIONAL / SCIENCE & HEALTH

LIVESCENCE Child Flu Deaths Hit Record High for This Time of Year Jan. 7, 2020

THE WALL STREET JOURNAL The Flu Season May Yet Turn Ugly, CDC Warns Jan. 8, 2019

FORTUNE Another Flu Pandemic Is Inevitable, World Health Organization Says Mar. 11, 2019

18

COCRYSTAL
PHARM, INC.



CC-42344: Influenza A Pandemic Antiviral Drug

Influenza A Crystals



- Binds to the highly conserved pocket on replication enzyme
- Exhibits broad spectrum activity against seasonal and pandemic influenza strains
- Favorable preclinical safety profile and pharmacokinetic properties
- Multiple routes of administration to include oral, inhalation and injection

Achieved Milestones and Next Steps:

- ✓ Q2 2020 Secured Supply Line
- ✓ Q3 2020 Initiated 2nd Batch of API Synthesis
- Q3 2021 Initiate Phase 1 Study

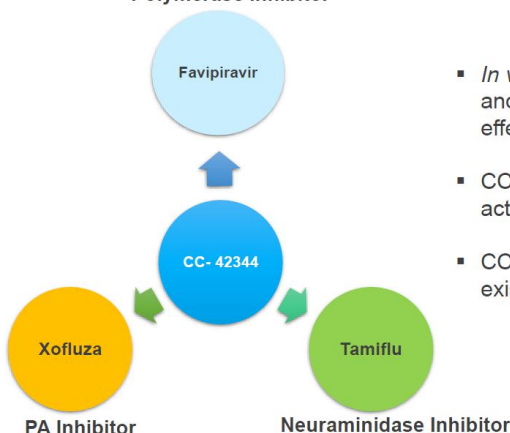
19

COCRYSTAL
PHARMA, INC.



CC-42344 Shows Strong Synergistic Effects with Approved Influenza Antivirals

Polymerase Inhibitor



- *In vitro* combination studies with Xofluza, Tamiflu, and Favipiravir demonstrated strong synergistic effects
- CC-42344 shows high barrier to drug resistance and active against known resistant influenza strains
- CC-42344 is promising cocktail candidate with existing influenza antivirals

20

COCRYSTAL
PHARMA, INC.



CC-42344: Pharmacological, Safety, Toxicity and PK Evaluations Successfully Completed

- ✓ *In vitro* antiviral profiling against seasonal and pandemic influenza A strains
- ✓ Cytotoxicity including larger screen: HepG2/high content analysis and 13 cell lines
- ✓ Caco-2 bidirectional permeability
- ✓ CYP inhibition (HLM): inhibition (2D6, 3A, 1A, 2B6, 2C8, 2C9, 2C19) & time dependent inhibition (2D6, 3A4)
- ✓ Thermodynamic/aqueous solubility
- ✓ pION solubility determination (at pH 7.4)
- ✓ Metabolic stability in rat and human microsomes (intrinsic clearance)
- ✓ Plasma protein binding (human)
- ✓ Plasma stability/half-life determination (human, rat)
- ✓ Pharmacokinetics: in rats (IV/PO), mouse (IV/PO) and dogs (IV/PO)
- ✓ *In silico* genotoxicity /carcinogenicity
- ✓ Off-target: kinase/receptor profiling; safety screen (CEREP)
- ✓ Mitochondrial toxicity (GLU/GAL)
- ✓ Mini Ames (genotox) screen
- ✓ Mini hERG (*in vitro* pharmacology) screen
- ✓ Exploratory 7-day mouse tox study (up to 500 mg/kg/day)

21

COCRYSTAL
PHARMA, INC.

Overview | Antiviral Program: Hepatitis C

22



Hepatitis C Strategy

Lead program CC-31244, Phase 2a study completed for the treatment of HCV

Current HCV Market Overview

- Ultrashort treatment strategy
- Limitations of existing long-term HCV therapies:
 - Longer period for virus to replicate and mutate, creating significant drug resistance challenges
 - Increased risk of adverse events
 - Greater opportunity for missed doses
- Multiple opportunities to develop shorter combination therapy with approved HCV drugs
- Proven rapid commercial success and market-share gains with shorter treatment regimens

Evolution of Shorter Therapy

Nucleoside/NS5A Inhibitors



Gilead's EPCLUSA®

12-week treatment
Approved June 2016

Protease/NS5A Inhibitors



AbbVie's Mavyret™

8-week treatment
Approved August 2017

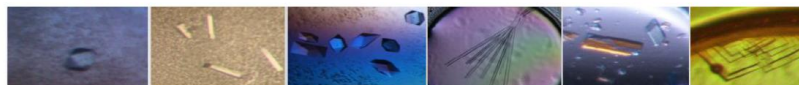
23

COCRYSTAL
PHARMACEUTICALS



CC-31244: HCV Non-Nucleoside Inhibitor (NNI)

HCV GT1 – GT6 NS5B Polymerase Crystals



Next Generation Combination (Cocktail) Therapy

- Potential best-in-class HCV NNI with a strong profile
- Broad-spectrum, potent NS5B polymerase inhibitor
- Effective against known NNI drug resistant variants
- Orally administered; liver targeting
- Ready for combination therapy clinical trials

Potential Best-in-Class NNI

Drug	Genotype	Dose (mg)	Treatment Frequency	Viral Load Reduction (Log ₁₀ U/ml)
CC-31244	Genotypes 1-6	400	QD	(3.0)
ABT-333 (Dasabuvir) [†]	Genotype 1	400	BID	(1.08)
		800	BID	(0.95)
GS-9190 (Tegobuvir)	Genotype 1	40	BID	(1.0)
		120	BID	(1.5)

24

COCRYSTAL
PHARMA, INC.



Favorable HCV Phase 2a Trial Results with CC-31244

- 6 weeks of Eplclusa® therapy including 2 weeks of CC-31244
- Treatment was well tolerated with no study discontinuations due to adverse events
- 8 of 12 subjects (67%) achieved both SVR12 and SVR24, considered virologic cure
- 4 patients had virologic relapse at Week 10, 4 weeks after completion of treatment
- 8 patients who achieved SVR had significantly higher frequency of CD8+ T cells compared with the 4 who relapsed, providing opportunities for personalized medicine

Achieved Milestones and Next Steps:

- ✓ Q1 2020 Final Report on Phase 2a U.S. Trial Filed with U.S. FDA
- Development Point Achieved; Seeking Partner for Further Development

25

COCRYSTAL
PHARMA, INC.

Overview | Antiviral Program:
Norovirus Gastroenteritis

26



Norovirus: No Approved Treatment

Norovirus Polymerase and Protease Crystals



Estimated annual cost of \$60 billion worldwide due to healthcare costs and lost productivity¹

~685 Million
infections worldwide annually¹

19-21 Million
cases in the U.S.¹

465,000
emergency department visits in the U.S.¹

109,000
hospitalizations in the U.S.¹

1. CDC, Norovirus Disease in the United States, 2020

27

COCRYSTAL
PHARMA, INC.



Potential for Developing First Norovirus Therapy

- Potent, broad-spectrum polymerase and protease inhibitors licensed from KSURF
- Structure-based lead molecule discovery ongoing

Achieved Milestones and Next Steps:

- ✓ Q2 2020 Filed Additional Patent Application
- H1 2021 Complete Proof-of-Concept Animal Study

28

COCRYSTAL
PHARMA, INC.

Positioned for Growth

29

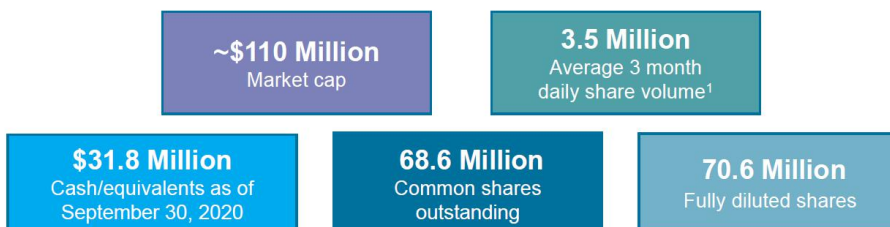


Expanding Intellectual Property Portfolio

- **Influenza A/B**
 - Influenza A/B inhibitor
 - Pending applications in U.S. and worldwide
 - **Coronavirus**
 - Issued patents in U.S. and major countries
 - Pending U.S. provisional applications
 - **Pandemic Influenza A**
 - PB2 (influenza A inhibitor)
 - Pending applications in PCT and Taiwan
 - Pending U.S. provisional applications
- HCV**
 - NS5B (NNI)
 - Issued patents in U.S.
 - Pending applications in U.S. and worldwide
 - Pending U.S. provisional application
 - **Norovirus**
 - Issued patents in U.S. and major countries
 - Pending U.S. provisional applications



Financial Snapshot



- Clean balance sheet
 - No preferred shares
 - No debt
 - Only 243,000 warrants
- ~\$800,000/month 2021 cash burn
- Cash runway beyond 2022

¹ Yahoo Finance, 3-month daily volume



Investment Highlights

- Applying proprietary structure-based drug design technology to develop first- and best-in-class broad-spectrum antiviral drugs
- Large market opportunities for the treatment of acute and chronic viral diseases including seasonal and pandemic influenza, COVID-19, hepatitis C, and norovirus gastroenteritis
- Product candidates are tested for multiple routes of delivery
- Robust development pipeline including Merck collaboration
- Seasoned leadership includes two Nobel laureates and biotech veterans with proven success in drug discovery and development, business and finance
- Cost-efficient business model supported by strong cash position and clean capital structure

