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 23, 2022

Cocrystal Pharma, Inc.
(Exact name of registrant as specified in its charter)

Delaware	001-38418	35-2528215
(State or other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

19805 N. Creek Parkway Bothell, WA	98011
(Address of principal executive offices)	(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:

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

Item 2.02 Results of Operations and Financial Condition

On March 23, 2022, Cocrystal Pharma, Inc. (the "Company") issued a press release announcing its results of operations for the fiscal year ended December 31, 2021. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information contained in this Item 2.02, including Exhibit 99.1 attached hereto, is being furnished and shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, or otherwise subject to the liabilities of that section. Furthermore, the information contained in this Item 2.02 or Exhibit 99.1 shall not be deemed to be incorporated by reference into any registration statement or other document filed pursuant to the Securities Act of 1933, except as shall be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit	Description
99.1	Press Release dated March 23, 2022
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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 23, 2022

By: */s/ James Martin*
Name: James Martin
Title: Chief Financial Officer and Co-Interim Chief Executive Officer

Cocrystal Pharma Reports 2021 Financial Results and Provides Updates on Development Programs and Milestones

- Commenced enrollment in Phase 1 trial with orally administered, broad-spectrum antiviral agent *CC-42344* for the treatment of pandemic and seasonal influenza A
- Advanced COVID-19 programs with the goal of initiating two Phase 1 trials in 2022 with the intranasal/pulmonary antiviral *CDI-45205* and an orally administered antiviral agents
- Selected two promising COVID-19 oral antiviral leads for further evaluation, with both demonstrating activity against SARS-CoV-2 and variants of concern
- Merck continues development of influenza A/B compounds under an exclusive worldwide license and collaboration agreement

BOTHELL, Wash. (March 23, 2022) – Cocrystal Pharma, Inc. (Nasdaq: COCP) reports financial results for the 12 months ended December 31, 2021, and provides updates on its antiviral pipeline, upcoming milestones and business activities.

"This is an eventful time at Cocrystal as we thoughtfully advance our antiviral programs for the treatment of influenza and COVID-19," said Sam Lee, Ph.D., co-interim CEO and President of Cocrystal. "Enrollment is underway in our Phase 1 trial in Australia with our antiviral compound *CC-42344* for pandemic and seasonal influenza A, keeping us on track for data readout later this year.

"We affirm plans to initiate first-in-human clinical studies as soon as possible in 2022 with two SARS-CoV-2 protease inhibitors, including our inhalation/pulmonary compound *CDI-45205* and an orally administered compound," Dr. Lee added. "Early this year, we received extensive comments from the U.S. Food and Drug Administration (FDA) on our pre-IND briefing package for *CDI-45205* that provide valuable information in designing Phase 1 and Phase 2 studies for both*CDI-45205* and our orally administered program."

"We continue advancing multiple high-value antiviral compounds into clinical development and remain opportunistic," said James Martin, co-interim CEO and CFO. "Importantly, given current markets and world economic stability conditions, we continue to be well positioned to execute on our strategy with a clean capital structure and a cash balance we believe is sufficient to fund planned operations through 2023."

Antiviral Pipeline Overview

Many antiviral drugs are effective only against certain strains of a virus and are less effective or not effective at all against other strains. Cocrystal is developing drug candidates that specifically target proteins involved in viral replication. Despite the various strains of virus that may exist or emerge, these enzymes are required for viral replication and are essentially similar (highly conserved) among all strains. By targeting these highly conserved regions of the replication enzymes, our antiviral compounds are designed and tested to be effective against major virus strains.

COVID-19 and Other Coronavirus Programs

By targeting viral replication enzymes and protease, we believe it is possible to develop an effective treatment for all coronavirus diseases including COVID-19, Severe Acute Respiratory Syndrome (SARS) and Middle East Respiratory Syndrome (MERS). Our main SARS-CoV-2 protease inhibitors showed potent *in vitro* pan-viral activity against common human coronaviruses, rhinoviruses and respiratory enteroviruses that frequently cause the common cold, as well as against noroviruses that can cause symptoms of acute gastroenteritis.

- *Intranasal/Pulmonary Protease Inhibitor CDI-45205*
  - We received guidance from the FDA regarding further development of *CDI-45205*, our novel SARS-CoV-2 main protease inhibitor as a potential treatment for COVID-19 and its variant via intranasal/pulmonary delivery. The guidance provides a clearer pathway for our planned Phase 1 single-ascending-dose and multiple-ascending-dose study that we expect to initiate in 2022, as well as directives for designing a subsequent Phase 2 study.
  - *CDI-45205* and several analogs showed potent *in vitro* activity against the SARS-CoV-2 Omicron (Botswana and South Africa/BA.1), Delta (India/B.1.617.2), Gamma (Brazil/P.1), Alpha (United Kingdom/B.1.1.7) and Beta (South Africa/B.1.351) variants, surpassing the activity observed with the original (wild-type) Wuhan strain.
  - *CDI-45205* demonstrated good bioavailability in mouse and rat pharmacokinetic studies via intraperitoneal injection, and no cytotoxicity against a variety of human cell lines. *CDI-45205* also demonstrated a strong synergistic effect with the FDA-approved COVID-19 medicine remdesivir.
  - *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. We believe the protease inhibitors obtained from KSURF have the ability to inhibit the inactive SARS-CoV-2 polymerase replication enzymes into an active form.

- *Oral Protease Inhibitors*
  - We selected investigational novel antiviral drug candidates *CDI-988* and *CDI-873* for further development as potential oral treatments for COVID-19. Both candidates were designed and developed using our proprietary structure-based drug discovery platform technology. These agents are chemically differentiated and exhibit superior *in vitro* potency again SARS-CoV-2, with activity maintained against current variants of concern. Both candidates demonstrated a favorable safety profile and pharmacokinetic properties that are supportive of daily oral dosing.
  - We plan to initiate a Phase 1 trial as soon as possible in 2022 with one of these candidates. We believe the FDA's guidance for further development of *CDI-45205* provides us with a clearer pathway for the clinical development of our oral COVID-19 program.

- *Replication Inhibitors*
  - We are using our proprietary structure-based drug discovery platform technology to discover replication inhibitors as orally administered therapeutic and prophylactic treatments for SARS-CoV-2. Replication inhibitors hold potential to work with protease inhibitors in a combination therapy regimen.

Influenza Programs

The global market for influenza therapeutics is expected to reach nearly $6.5 billion by 2022, according to a report published by BCC Research in May 2018.

- *Pandemic and Seasonal Influenza A*
  - Earlier this month we announced dosing of the first subjects in the Phase 1 clinical trial with *CC-42344*. A novel PB2 inhibitor, *CC-42344* has shown excellent antiviral activity against influenza A strains, including pandemic and seasonal strains, as well as strains resistant to Tamiflu and Xofluza. *CC-42344* also has favorable pharmacokinetic and drug-resistance profiles. We expect to report data on the Phase 1 clinical trial in 2022.

- *Pandemic and Seasonal Influenza A/B program*

  - In January 2019 we entered into an Exclusive License and Research Collaboration Agreement with Merck Sharp & Dohme Corp. to discover and develop certain proprietary influenza antiviral agents that are effective against both influenza A and B strains. This agreement includes milestone payments of up to $156 million plus royalties on sales of products discovered under the agreement.
  - In January 2021 we announced completion of all research obligations under the agreement. Merck is now solely responsible for further preclinical and clinical development of the influenza A/B antiviral compounds discovered under this agreement.
  - Merck continues development activities with the antiviral influenza A/B compounds discovered under this agreement.

Norovirus Program

- We are developing certain proprietary broad-spectrum antiviral compounds to treat norovirus infections.
- Norovirus is a global public health problem responsible for nearly 90% of epidemic, non-bacterial outbreaks of gastroenteritis around the world.

Hepatitis C Program

- We are seeking a partner to advance the development of *CC-31244* following completion of a Phase 2a trial. This compound has shown favorable safety and preliminary efficacy in a triple-regimen Phase 2a study in combination with Epclusa (sofosbuvir/velpatasvir) for the ultra-short duration treatment of individuals infected with the hepatitis C virus (HCV).
- HCV is a viral infection of the liver that causes both acute and chronic infection. The 2017 World Health Organization Global Hepatitis Report estimates that 71 million people worldwide have chronic HCV infections.

2021 Financial Results

Throughout 2020 Cocrystal reported revenues under an influenza A/B collaboration with Merck consisting of research and development (R&D) services performed by Cocrystal and reimbursed by Merck. As discussed above, 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 2021 compared with $2.0 million in revenues for 2020. Under the terms of the Merck collaboration, Cocrystal is eligible to receive up to $156 million in payments related to designated developments, regulatory and sales milestones, as well as royalties on product sales.

R&D expenses for 2021 were $8.8 million compared with $6.0 million for 2020, with the increase primarily related to COVID-19 and influenza programs. The Company expects R&D expenses to increase during 2022 due to the advancement of our influenza A program into the clinic and progress with preclinical COVID-19 programs toward clinical development. General and administrative expenses for 2021 were $5.4 million compared with $5.6 million for 2020, with the decrease primarily due to reduced professional fees resulting from the conclusion of certain previously reported legal matters.

The net loss for 2021 was $14.2 million, or $0.16 per share, compared with a net loss for 2020 of $9.6 million, or $0.17 per share.

The Company reported unrestricted cash of $58.7 million as of December 31, 2021, compared with $33.0 million as of December 31, 2020. Net cash used in operating activities for 2021 was $12.7 million. During 2021 the company raised $38.5 million, net of transaction costs, which included net proceeds of approximately $2.1 million from the sale of common stock through an At-The-Market (ATM) facility in January 2021 and $36.4 million in net proceeds from a public offering of common stock May 2021. The Company reported working capital of $57.8 million as of December 31, 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.

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 our goals of initiating two Phase 1 studies for our COVID-19 programs in 2022, our expectations of reporting data from the Phase 1 clinical study of our Influenza A product candidate later in 2022, the viability and efficacy of potential treatments for coronavirus and other diseases, expectations for the global market for influenza therapeutics, our attempts to discover replication inhibitors, our development of antiviral treatments for norovirus, our expectations concerning R&D expenses, the expected sufficiency of our cash balance to fund our planned operations through 2023 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, the risks arising from the impact of the COVID-19 pandemic and/or the Ukraine war on our Company, our collaboration partners, and on the national and global economy, including manufacturing and research delays arising from raw materials and labor shortages, supply chain disruptions and other business interruptions including and adverse impacts on our ability to obtain raw materials and test animals as well as similar problems with our vendors and our current Clinical Research Organization (CRO) and any future CROs and Contract Manufacturing Organizations (CMOs), the ability of our current CRO to recruit volunteers for, and to proceed with, clinical trials, possible delays resulting from future lockdowns in Australia, 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, development of effective treatments and/or vaccines by competitors, including as part of the programs financed by the U.S. government, potential mutations in a virus we are targeting which may result in variants that are resistant to a product candidate we develop, and any additional costs related to unfavorable future outcome of pending litigation or any unanticipated claims. 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, 2021. 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

Media Contact:

JQA Partners
Jules Abraham
917-885-7378
Jabraham@jqapartners.com

Financial Tables to follow

COCRYSTAL PHARMA, INC.

CONSOLIDATED BALANCE SHEETS
(in thousands)

	December 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash	$ 58,705	$ 33,010
Restricted cash	50	50
Accounts receivable	-	556
Prepaid expenses and other current assets	568	399
Total current assets	59,323	34,015
Property and equipment, net	453	591
Deposits	46	46
Operating lease right-of-use assets, net (including $153 to related party)	478	498
Goodwill	19,092	19,092
Total assets	$ 79,392	$ 54,242
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 1,297	$ 1,080
Current maturities of finance lease liabilities	27	39
Current maturities of operating lease liabilities (including $53 to related party)	209	178
Derivative liabilities	12	61
Total current liabilities	1,545	1,358
Long-term liabilities:		
Finance lease liabilities	7	34
Operating lease liabilities (including $101 to related party)	291	345
Total long-term liabilities	298	379
Total liabilities	1,843	1,737
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.001 par value; 150,000 and 100,000 shares authorized as of December 31, 2021 and December 31, 2020, respectively; 97,469 and 70,439 shares issued and outstanding as of December 31, 2021 and December 31, 2020, respectively	98	71
Additional paid-in capital	336,544	297,342
Accumulated deficit	(259,093)	(244,908)
Total stockholders' equity	77,549	52,505
Total liabilities and stockholders' equity	$ 79,392	$ 54,242

COCRYSTAL PHARMA, INC.

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

	December 31,	
	2021	2020
Revenues:		
Collaboration revenue	$ -	$ 2,014
Operating expenses:		
Research and development	8,794	6,034
General and administrative	5,427	5,566
Total operating expenses	14,221	11,600
Loss from operations	(14,221)	(9,586)
Other (expense) income:		
Interest expense, net	(4)	(8)

Change in fair value of derivative liabilities	49	(54)
Foreign exchange loss	(9)	-
Total other income (expense), net	36	(62)
Net loss	$ (14,185)	$ (9,648)
Net loss per common share:		
Loss per share, basic and diluted	$ (0.16)	$ (0.17)
Weighted average number of common shares outstanding, basic and diluted	88,368	55,217

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