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Zacks Small-Cap Research

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Cocrystal Pharma, Inc. (COCP-NASDAQ)

UPDATE: Cocrystal Pharma announced several program updates and investor events.

Utilizing a DCF valuation process containing conservative estimates combined with other valuation methodologies, we believe COCP could be worth $9.00. There is a wide range of outcomes which could materially increase or decrease our target price.

Current Price (3/21/23)	$1.87
Valuation	**$9.00**

OUTLOOK

Cocrystal Pharma is a clinical stage biotechnology company focused on novel antiviral treatments in the areas of coronavirus, influenza, hepatitis, and norovirus. The company has a proprietary drug discovery platform technology that provides more rapid and efficient drug discoveries. The company has a seasoned management team and an experienced science advisory board that includes two Nobel laureates. Cocrystal has been successful at raising capital throughout its history and runs a cost-efficient operation with a clean capital structure and no debt. We believe that the company has sufficient funding for planned operations through 2023.

SUMMARY DATA

52-Week High	**$7.44**
52-Week Low	**$1.74**
One-Year Return (%)	**-72.5**
Beta	**0.70**
Average Daily Volume (sh)	**55,837**
Shares Outstanding (mil)	**8.14**
Market Capitalization ($mil)	**$15.3**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**16.0**
Insider Ownership (%)	**25.3**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2022 Estimate	**N/A**
P/E using 2023 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**High**
Type of Stock	**Small-Growth**
Industry	**Biotechnology**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2020	0.46 A	0.55 A	0.49 A	0.51 A	2.01 A
2021	0.00 A	0.00 A	0.00 A	0.00 A	0.00 A
2022	0.00 A	0.00 A	0.00 A	0.00 E	0.00 E
2023	1.00 E	1.30 E	1.70 E	1.90 E	6.00 E

Adjusted EPS / Loss Per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2020					
2021					
2022	-$0.52 A	-$0.46 A	-$0.70 A	-$0.73 E	-$2.41 E
2023	-$0.67 E	-$0.71 E	-$0.64 E	-$0.64 E	-$2.66 E

Quarterly revenues may not equal annual revenues due to rounding.
Quarterly EPS may not equal annual EPS due to rounding or dilution.

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WHAT'S NEW

Program Updates & Additional News

Cocrystal Pharma to Highlight Progress with Its Antiviral Portfolio at the Virtual Investor Summit on March 29, 2023 – The company announced that James Martin, CFO and co-CEO, will present a company overview at the Virtual Investor Summit Conference being held on Wednesday, March 29, 2023 at 10:30 a.m. Eastern time.

"This is a highly eventful time a Cocrystal with significant advancements and upcoming milestones with our antiviral influenza A, COVID-19 and norovirus programs," said Mr. Martin. "We look forward to sharing our progress with the many investors tuning into this event."

Cocrystal Pharma Reports Highly Favorable Safety and Tolerability Results from a Phase 1 Study with its Oral Antiviral CC-42344 for the Treatment of Pandemic and Seasonal Influenza A – The company announced highly favorable safety and tolerability results for its orally administered replication inhibitor CC-42344 in its Phase 1 study. CC-42344 is a broad-spectrum antiviral for the treatment of pandemic and seasonal influenza A with a novel mechanism of action. The randomized, double-controlled Phase 1 study was conducted in Australia to evaluate the safety, tolerability and pharmacokinetics (PK) of CC-42344 given orally at single doses up to 800 mg and daily doses up to 14 days in 56 healthy volunteers.

Approximately 50% of the participants who received a single dose of CC-42344 across all dose levels (100 to 800 mg) experienced adverse events, similar to the proportion of placebo subjects who also experienced adverse events. In the multiple-dose section of the study, the incidence of adverse events was 67% for both CC-42344 (50 to 200 mg) and placebo. The vast majority of adverse events were mild in severity. The most frequently reported adverse event was headache, which occurred at similar rates in CC-42344-treated and placebo-treated participants. There were no serious adverse events or drug discontinuation due to adverse events.

"We are encouraged by the highly favorable safety and tolerability results from this first-in-human study with CC-42344. These findings give us confidence to continue our clinical testing of this compound as a potential treatment for pandemic and seasonal influenza A," said Sam Lee, Ph.D., Cocrystal's President and co-interim CEO. *"With these results our influenza A program has achieved a major milestone and we look forward to beginning a Phase 2a clinical study."*

Cocrystal plans to apply to the United Kingdom Medicines and Healthcare Products Regulatory Agency to conduct a Phase 2a human challenge study in early 2023. Subject to regulatory clearance, the study is expected to be initiated in the second half of 2023.

Previous Updates & News

Pandemic and Seasonal Influenza A – In March 2022, Cocrystal initiated enrollment in a Phase 1 study with orally administrated antiviral CC-42344 in healthy adults. This randomized, double-controlled, dose-escalating study is designed to assess the safety, tolerability and pharmacokinetics of CC-42344.

In April 2022, the company announced preliminary data from its Phase 1 study with CC-42344, which demonstrated a favorable safety and pharmacokinetic profile in the first two cohorts administered single-ascending doses of 100 mg and 200 mg. The company expects to complete this Phase 1 clinical study and report relevant data in 2022.

On July 14th, the company announced that pharmacokinetic (PK) data from the single ascending dose portion of a Phase 1 study with its novel, broad-spectrum, orally administered antiviral candidate CC-

42344 for the treatment of pandemic and seasonal influenza A support the potential for once-daily dosing. The single ascending dose portion of the Phase 1 study has been completed and subjects are currently being enrolled in the multiple ascending dose portion of the Phase 1 study.

“The PK data from single ascending dose portion of the trial mark a major milestone in the development of CC-42344’s as our drug holds potential to be administered once a day, less frequently than the leading influenza treatment Tamiflu®,” said President and co-interim CEO Sam Lee. “Unlike the mechanism of action of existing influenza A treatments, CC-42344 is a PB2 inhibitor that blocks an essential step of influenza viral replication and transcription. Completed in vitro testing demonstrated potent antiviral activity against prevalent influenza A strains that are resistant to the two approved influenza treatments Tamiflu® and Xofluza®.”

In November 2022 the company announced the Phase 1 study had reached full enrollment and reiterated expectations to report topline results in 2022. Additionally, the company entered into an agreement with a UK-based clinical research organization to conduct a human challenge Phase 2a study evaluating safety, viral and clinical measures of orally administered CC-42344 in influenza A-infected subjects. Under the human challenge model, healthy adults will be infected with the influenza A virus under carefully controlled conditions, which we believe will hasten trial enrollment and ensure subjects are infected with influenza A.

The company expects to submit an application with the United Kingdom Medicines and Healthcare Products Regulatory Agency in early 2023 to conduct a human challenge Phase 2a study. Pending clearance by the agency, the company expects to initiate the study in the second half of 2023.

Intranasal/Pulmonary Protease Inhibitor CDI-45205 – This is the company’s novel SARS-CoV-2 3CL (main) protease inhibitor being developed as a potential treatment for COVID-19 and its variants via intranasal/pulmonary delivery. The company has initiated scale-up synthesis and process chemistry development with CDI-45205 in order to assemble data to support an IND application with the goal of progressing to a first-in-human clinical trial in 2022.

In January 2022, Cocrystal received guidance from the FDA regarding further preclinical and clinical development of CDI-45205 that provides them with a clearer pathway for the Phase 1 study that is expected to commence at some point in 2022, as well as directives for designing a subsequent Phase 2 study.

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. The company still believes the protease inhibitors obtained from KSURF have the ability to inhibit the inactive SARS-CoV-2 polymerase replication enzymes into an active form.

In April 2022, the company announced a collaboration with the National Institute of Allergy and Infectious Diseases (NIAID) to evaluate the potential of the COVID-19 3CL protease inhibitors for the treatment of COVID-19, with the NIAID responsible for in vitro and in vivo studies evaluating the antiviral activity of the compounds. In June 2022 the company expanded this collaboration by providing our proprietary process chemistry information for oral 3CL protease inhibitors to the NIAID to support scale-up synthesis of a key intermediate of these compounds.

Oral Protease Inhibitors CDI-988 and CDI-873 – During the quarter, the company selected CDI-988 as the lead candidate for development as a potential oral treatment for SARS-CoV-2. CDI-988, which was designed and developed using our proprietary structure-based drug discovery platform technology, targets a highly conserved region in the active site of SARS-CoV-2 3CL (main) protease required for viral

RNA replication. CDI-988 exhibits superior in vitro potency against SARS-CoV-2 with activity maintained against current variants of concern and demonstrated a safety profile and PK properties that are supportive of daily dosing.

The company is currently conducting good laboratory practice (GLP) toxicology studies in preparation for a Phase 1 study and plans to initiate a Phase 1 study in the first quarter of 2023. The company believes the FDA's guidance for further development of their antiviral candidate CDI-45205 provides them with a clearer pathway for a planned Phase 1 study with CDI-988, as well as directives for designing a subsequent Phase 2 study.
Pandemic and Seasonal Influenza A/B program - In January 2019, Cocrystal entered into an Exclusive License and Research Collaboration Agreement with Merck 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, the company announced they had completed all of their 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 developmental activities with the antiviral influenza A/B compounds the company discovered under this agreement.

Valuation & Estimate Changes

The company's current cash position of $42.0 million should be sufficient to fund their operations through the end of 2023, and possibly into 2024, depending on R&D spending levels and possible milestone payments from Merck.

We will update our earning estimates and valuation target pending review of the company's 2022 10-K filing and other material updates.

KEY INVESTMENT POINTS

- Founded in 2006, Cocrystal Pharma (COCP) is a clinical stage biotechnology firm headquartered in Bothell, WA with approximately 13 employees at this time.

- The company's product pipeline targets large addressable markets globally for the effective treatment of acute and pandemic viral diseases. These technologies are designed to efficiently deliver small molecule therapeutics that are safe, effective, and convenient to administer.

- Cocrystal has a strong and promising therapeutic drug development pipeline covering treatments for Covid-19, influenza, hepatitis, and norovirus. At this time, the company has not pursued antiviral vaccine development.

- The company has developed a proprietary drug discovery platform technology that accelerates the timeline for drug discovery and development. This technology has been largely developed based on the work of Nobel laureate Roger Kornberg, PHD.

- Phase 1 clinical trials are expected to commence in 2022 for three of the company's drug development programs including two for the treatment of Covid-19 and one for Influenza A.

- A collaboration with Merck related to influenza A/B treatments has the potential to generate up $156 million in milestone payments and royalties and further validates Cocrystal's advanced drug discovery platform.

- The company has been successful in accessing the equity capital markets over the past 24 months raising approximately $74 million in cash to fund future operations.

- We believe Cocrystal has cash and available liquidity to fund current planned operations until 2023.

OVERVIEW

COCRYSTAL PHARMA, INC.

Source: cocrystalpharma.com/

Cocrystal Pharma is a pre-revenue, clinical-stage biotechnology company that is leveraging its core competencies and decades of management experience in antiviral therapeutics to fight not only the global Covid-19 health crisis, but other complex and problematic viral related infections and disease.

Founded in 2006 by Gary Wilcox (d. 2021), Dr. Sam Lee, Roger Kornberg and Philip Frost, the company focuses on therapeutics and treatments for serious or chronic viral diseases. The company has pursued both therapeutic and prophylactic avenues of fighting viral diseases, but not in the vaccine market as that area is currently established and competitive. Preventing viral replication is a key tenet of the company's research and development.

The company was originally privately funded by entrepreneur and pharmaceutical executive Dr. Phillip Frost who was involved with Ivax Corporation and Teva Pharmaceuticals. Cocrystal went public in 2014 through a reverse merger with an existing shell company at the time. In 2015, they merged with RFS Pharma, a privately owned biotech company founded by renowned drug developer, Dr. Raymond Schinazi. The company has generally been successful at raising capital through equity financing transactions since going public. More recently, in 2021 the company raised $38.5 million through a normal course secondary offering under a current shelf registration. Additionally, in 2020, they raised $35.8 million through a secondary ATM offering.

The company has developed a proprietary drug discovery platform technology that provides potential for viable drug candidates at reduced costs and with shorter discovery and development timelines. This involves utilizing high throughput x-ray crystallography at near atomic resolution to deliver potent and effective molecules that can evade viral resistance.

Cocrystal currently has seven active programs in its product pipeline of which three of these are devoted to treatments for SARS-CoV-2. Two programs are related to effective antiviral treatments for pandemic and seasonal influenza infections and one is a legacy approach to shortening treatments for Hepatitis C. The final program deals with Norovirus Gastroenteritis, a highly contagious widespread virus that causes diarrhea, nausea and stomach pain.

The company has been successful in creating a growing patent portfolio wall that protects its research and covers the areas of coronavirus, pandemic influenza, seasonal influenza, norovirus and hepatitis C. Cocrystal has issued patents, or pending patent applications in the U.S. and around the world.

Although the path to commercialization of its drug prospects may be long as it progresses through its pre-clinical development and clinical trials, the company is confident it has the capital to fund currently planned operations. The option to license its discoveries to larger pharmaceutical or biotechnology companies remain a viable option which would occur on a closer time frame than commercialization.

In the Influenza A program, the patent portfolio consists of four patent families, including two pending international (PCT) applications and two families of pending applications in the U.S. and various foreign countries.

In the Influenza A/B program, the patent portfolio consists of a number of patent families pending, variously, as international (PCT) applications and in Taiwan. Aspects of this program are developed in collaboration with Merck.

In the Norovirus and Coronavirus programs, the patent portfolio consists of three pending families of U.S. provisional applications, and a portfolio of patent families licensed through KSURF.

RISK FACTORS

- The company have never generated revenue from product sales and all product candidates are currently in the pre-clinical and early clinical stage. The ability to generate revenue from product sales and achieve profitability depends on their ability, alone or with partners, to successfully complete the development of, obtain the regulatory approvals for, and commercialize pharmaceutical product candidates.

- The company may continue to incur significant losses for the foreseeable future and never generate revenue from product sales. As an early-stage drug development company, the company's focus is on developing product candidates, obtaining regulatory approvals, and commercializing pharmaceutical products. As a result, the company has an accumulated deficit of $259,093,000 from inception through December 31, 2021.

- The company's Covid-19 program is in the preclinical stage. The company initiated preclinical studies during the second quarter of 2020 and selected the lead preclinical molecule in the fourth quarter of 2020. The company may be unable to produce an effective therapy in a timely manner or at all. Additionally, they are committing substantial financial and other resources to the Covid-19 program, which may negatively impact other drug development programs.

- Many of the company's competitors that are also developing treatments for the Covid-19 virus, and other viruses, have substantially more resources including government funding than the company does and have existing products in significantly more advanced stages of development.

- The company relies on 3rd parties for many, or all aspects of compound formulation, research and preclinical testing. These included Clinical Research Organizations (CROs) as well as outside organizations that own and maintain advanced devices for x-ray crystallography.

- The company relies on a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to future products and drug product candidates. The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The owned patent applications may fail to result in patents with claims that cover the products in the United States or in other countries.

- The company will continue to generate significant operating losses for the foreseeable future and likely until its drug products reach commercialization or licensure arrangements. Capital financing to support

these losses, either from the equity or debt markets, may not always be available based on economic or market conditions.

VALUATION

Our primary valuation tool utilizes a Discounted Cash Flow process and produces three different scenarios.

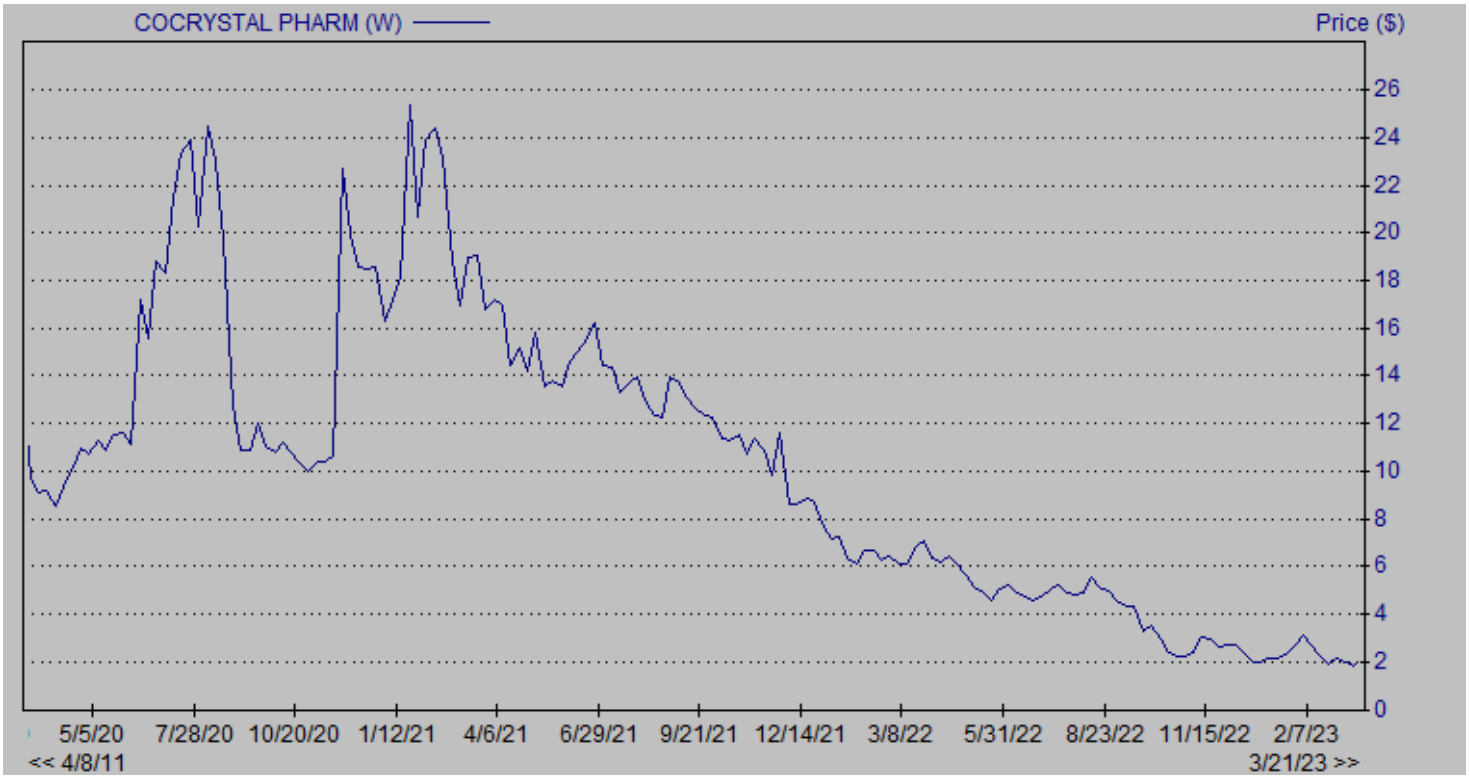
Bull Case – The company experiences some form of success in all of its seven key programs currently in the development pipeline over a 10-year time frame. This includes full realization of the $156 million in Merck milestone payments related to the Influenza A/B program. It also assumes commercialization revenues or partnership licensure revenues from the Oral and Nasal Covid-19 treatment programs will occur starting in 2024 and will become a material source of revenues in 2025. The value in this scenario is $12.39 and we apply a probability factor of 45%.

Base Case – The company experiences success in programs currently planned for clinical trials over the next 12-18 months but does not make progress in programs currently in pre-clinical or lead discovery phase. The value in this scenario is $7.80 and we apply a probability factor of 40%.

Bear Case – The company fails to create material revenue or profit opportunities over the next five years in the majority of its drug development programs and must raise additional equity capital. The value in this scenario is the current stock price of $3.00 and we apply a probability factor of 15%.

The weighted average price target of these three scenarios is **$9.00**. It is notable that the DCF calculation incorporates a 20% discount rate due to higher prevailing global interest rates.

HISTORICAL STOCK PRICE



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