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Zacks Small-Cap Research

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Cocrystal Pharma, Inc. (NASDAQ:COCP)

COCP: Cocrystal provides updates on its clinical programs. We lower our price target to $4.00 per share to account for the absence of Merck milestone payments.

Utilizing a DCF valuation process containing conservative estimates combined with other valuation methodologies, we believe COCP could be worth **$4.00**. There is a wide range of outcomes which could materially increase or decrease our target price.

Current Price (2/16/24)	$1.57
Valuation	**$4.00**

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 the next 12 months.

SUMMARY DATA

52-Week High	**$3.29**
52-Week Low	**$1.38**
One-Year Return (%)	**-35.5**
Beta	**1.18**
Average Daily Volume (sh)	**16,208**
Shares Outstanding (mil)	**10.173**
Market Capitalization ($mil)	**$15.9**
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**

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)
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 A	0.00 A
2023	0.00 A	0.00 A	0.00 A	0.00 E	0.00 E
2024					0.00 E

Adjusted EPS / Loss Per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2021					
2022	-$0.52 A	-$0.46 A	-$0.70 A	-$0.55 A	-$2.33 A
2023	-$0.64 A	-$0.41 A	-$0.41 A	-$0.55 E	-$2.01 E
2024					-$2.05 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

- On January 8, 2024, Cocrystal Pharma released a new investor presentation which can be found here.

- On January 4, 2024, Cocrystal Pharma provided an update on the clinical development of its oral first-in-class pan-norovirus and pan-coronavirus dual protease inhibitor CDI-988 and its oral PB2 inhibitor CC-42344 for the treatment of pandemic and seasonal influenza A. CDI-988 and CC-42344 were specifically designed and developed using the company's unique structure-based drug discovery technology platform to be effective on a broad range of viruses causing these diseases.

  Cocrystal's President and co-CEO stated*, "We are encouraged that the preliminary data of the ongoing Phase 2a and Phase 1 studies showed CC-42344 and CD-988 were well-tolerated with favorable safety profiles. We see great promise with both of these drug candidates as potential effective oral treatments for highly contagious, pandemic viruses, while also providing significant market opportunities for Cocrystal."*

  CDI-988 targets a highly conserved region in the active site of the main 3CL protease required for viral RNA replication for pandemic norovirus and coronaviruses, including SARS-CoV-2. CDI-988 is being evaluated for safety and pharmacokinetics in a randomized, double-blinded, placebo-controlled Phase 1 study in healthy subjects being conducted in Australia. The company reports favorable preliminary data from the single-ascending dose cohorts of the clinical study. Cocrystal expects to report topline results from the Phase 1 study in 2024.

  CC-42344 binds to a highly conserved PB2 site of the influenza A polymerase complex and exhibits a novel mechanism of action that inhibits viral replication. A randomized, double-blind, placebo-controlled Phase 2a clinical study with CC-42344 is underway in the United Kingdom. The company reports favorable tolerability and safety in the first cohort of the Phase 2a influenza A challenge study and expects to report topline results from the Phase 2a clinical study in 2024. In 2022 Cocrystal reported favorable safety and tolerability results in the healthy volunteer Phase 1 study with CC-42344 conducted in Australia.

- On December 15, 2023, the company received written notice from Merck that they were electing to terminate the Exclusive License and Research Collaboration Agreement between Cocrystal and Merck concerning the collaboration on the development of influenza A/B antiviral compounds.

  The termination of the Agreement is effective on March 14, 2024. According to the termination notice, Merck determined there were no existing conditions to continue the collaboration. The termination resulted from the inability to develop the compounds to meet a specific aspect of Merck's program.

  Under the terms of the Agreement, Merck funded research and development of influenza A/B antiviral agents at the company and Merck, including clinical development at Merck, protecting intellectual property, and Merck was responsible for worldwide commercialization of any products derived from the collaboration.

  Cocrystal received an upfront payment of $4,000,000 in January 2019 and was eligible to receive milestone payments related to designated development, regulatory and sales milestones, as well as royalties on product sales. In January 2021, the company announced it had completed all research obligations under the Agreement, and that Merck was then solely responsible for further development of the influenza A/B antiviral compounds that were discovered in the collaboration. The pending patent applications on compounds covered by the Agreement and previously filed by Merck on behalf of both companies remain in place.

- On December 6, 2023, the company announced the achievement of first-patient-in for the Phase 2a human challenge clinical trial with CC-42344, an investigational new oral antiviral inhibitor for the treatment of pandemic and seasonal influenza A. This randomized, double-blind, placebo-controlled study will evaluate the safety, tolerability, viral and clinical measurements of influenza A infection in subjects dosed with oral CC-42344 treatment.

  Cocrystal's President and co-CEO Sam Lee stated, *"There is an urgent need for new oral antivirals targeting pandemic and seasonal influenza that address drug resistance. CC-42344 was discovered using our proprietary structure-based drug discovery platform technology to inhibit the viral replication process. The data from this proof-of-concept clinical study will further validate CC-42344's novel mechanism of action. We expect to report topline data from this clinical trial in 2024."*

  In late 2022 Cocrystal reported favorable safety and tolerability results in the single-ascending and multiple-ascending dose portions of the healthy volunteer Phase 1 trial conducted in Australia. Preclinical data showed that CC-42344 is highly active against seasonal and pandemic influenza A strains. In October 2023 Cocrystal received authorization from the United Kingdom Medicines and Healthcare Products Regulatory Agency to initiate a Phase 2a human challenge trial with CC-42344 as a potential treatment for pandemic and seasonal influenza A.

Valuation & Estimate Changes

The company's cash position of $29.7 million at the end of the 3rd quarter of 2023 should be sufficient to fund its operations through the next 12 months depending on R&D spending levels.

We adjust our 2024 and 2025 revenue and EPS estimates to account for the absence of any Merck milestone payments. Our 2024 estimates now call for zero revenues during the year and a loss per share of ($2.05).

We lower our price target to **$4.00** per share based on the recent updates.

Program Review

Cocrystal is developing antiviral therapeutics that inhibit the essential viral replication function of ribonucleic acid (RNA) viruses that cause acute and chronic diseases. The drug discovery process focuses on the highly conserved regions of the viral enzymes and inhibitor-enzyme interactions at the atomic level. It differs from traditional, empirical medicinal chemistry approaches that often require iterative high-throughput compound screening and lengthy hit-to-lead processes. By designing and selecting drug candidates that interrupt the viral replication process and have specific binding characteristics, the company seeks to develop drugs that are effective against both the virus and possible mutants of the virus, and also have reduced off-target interactions that may cause adverse side effects.

Influenza Programs

Influenza is a severe respiratory illness caused by either the influenza A or B virus that results in disease outbreaks mainly during the winter months. The global seasonal influenza market was valued at $6.5 billion in 2021 and is projected to reach up to $28.0 billion by 2029, according to Data Bridge Market Research.

Pandemic and Seasonal Influenza A

Cocrystal's novel oral PB2 inhibitor, CC-42344, has shown excellent antiviral activity against influenza A strains including pandemic and seasonal strains, as well as strains resistant to popular drugs Tamiflu® and Xofluza®.

In March 2022 the company initiated enrollment in a randomized, double-controlled, dose-escalating Phase 1 clinical trial to evaluate the safety, tolerability and pharmacokinetics (PK) of orally administered CC-42344 in healthy adults.

In April 2022 the company announced preliminary Phase 1 clinical trial data demonstrating a favorable safety and PK profile in the first two cohorts in the single-ascending dose portion of the study.

In July 2022 the company reported PK results from the single-ascending dose of the study supporting once-daily dosing.

In December 2022 the company reported favorable safety and tolerability results from the Phase 1 trial with CC-42344 for influenza A.

Cocrystal has entered into an agreement with a UK-based clinical research organization to conduct a Phase 2a human challenge study evaluating safety, and 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 is believed to accelerate the trial enrollment.

The company submitted an application to the United Kingdom Medicines and Healthcare Products Regulatory Agency to conduct the Phase 2a human challenge study and, pending clearance, is expected to initiate the study in the second half of 2023.

In addition, preclinical development is underway with an inhaled formulation of CC-42344 as a treatment and prophylaxis for influenza A. Phase 1 clinical trial for this is expected to commence in the 1st half of 2024.

COVID-19 and Other Coronavirus Programs

By targeting viral replication enzymes and protease, Cocrystal believes 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). The company's main SARS-CoV-2 protease inhibitors showed potent *in vitro* pan-viral activity against common human coronaviruses, rhinoviruses and respiratory enteroviruses that cause the common cold, as well as against noroviruses that can cause symptoms of acute gastroenteritis.

Oral Protease Inhibitor CDI-988

The company selected CDI-988 as our lead candidate for development as a potential oral treatment for SARS-CoV-2. Designed and developed using a proprietary structure-based drug discovery platform technology, CDI-988 targets a highly conserved region in the active site of SARS-CoV-2 3CL (main) protease required for viral RNA replication.

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

In May 2023 the company announced approval of an application to the Australian regulatory agency for a planned randomized, double-blind, placebo-controlled Phase 1 trial to evaluate the safety, tolerability and PK of oral CDI-988 in healthy volunteers.

The company believes the FDA's guidance for further development of antiviral candidate CDI-45205 (described below) also provides a clearer pathway for this study, as well as directives for designing a subsequent Phase 2 clinical trial.

In September 2023, the company dosed the first subject in the CDI-988 Phase 1 trial.

Intranasal/Pulmonary Protease Inhibitor CDI-45205

An IND-enabling study is ongoing with CDI-45205, a novel SARS-CoV-2 3CL (main) protease inhibitor being developed as a potential treatment for SARS-CoV-2 and its variants.

Guidance was received from the FDA regarding further preclinical and clinical development of CDI-45205 that provides a clearer pathway for future development.

CDI-45205 and several analogs showed potent in vitro activity against the main SARS-CoV-2 variants to date, surpassing the activity observed with the original Wuhan strain.

CDI-45205 demonstrated good bioavailability in mouse and rat PK 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. An IND-enabling study with CDI-45205 is ongoing.

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 April 2020. The company believes the protease inhibitors obtained from KSURF have the ability to inhibit the inactive SARS-CoV-2 polymerase replication enzymes into an active form.

Norovirus Program

The company is developing proprietary broad-spectrum, non-nucleoside polymerases for the treatment of human norovirus infections using a proprietary structure-based drug design technology platform. The company also holds exclusive rights to norovirus protease inhibitors for use in humans under the KSURF license. The company is targeting the selection of an oral preclinical lead in the first half of 2023.

In August 2023, the company announced the selection of the novel broad-spectrum 3CL protease inhibitor CDI-988 as the lead potential oral treatment for norovirus. CDI-988 is approved for evaluation in a first-in-human trial in healthy volunteers in Australia, and that trial is expected to serve as the Phase 1 trial for both the norovirus and coronavirus programs.

Norovirus is a global public health problem that's responsible for nearly 90% of epidemic, non-bacterial outbreaks of gastroenteritis around the world.

In September 2023, the company dosed the first subject in the CDI-988 Phase 1 trial.

Hepatitis C Program

Cocrystal is seeking a partner to advance the development of CC-31244 following the successful completion of a Phase 2a clinical trial. This compound has shown favorable safety and preliminary efficacy in a triple-regimen Phase 2a clinical trial 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. In June 2022 the World Health Organization estimated that 58 million people worldwide have chronic HCV infection.

KEY INVESTMENT POINTS

Source: cocrystalpharma.com/

- 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.
- 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 throughout the next 12 months.

OVERVIEW

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 remains a viable option which would occur in 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 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 has 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.

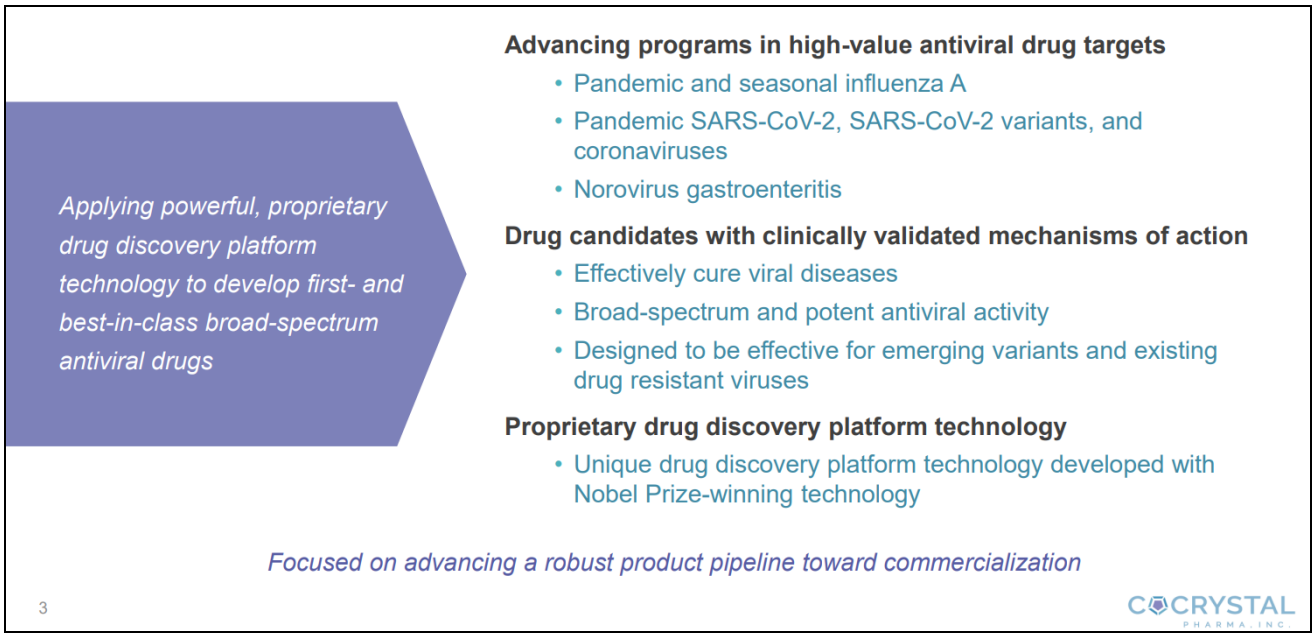
Additionally, they are committing substantial financial and other resources to the Covid-19 program, which may negatively impact other drug development programs.

- 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 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.



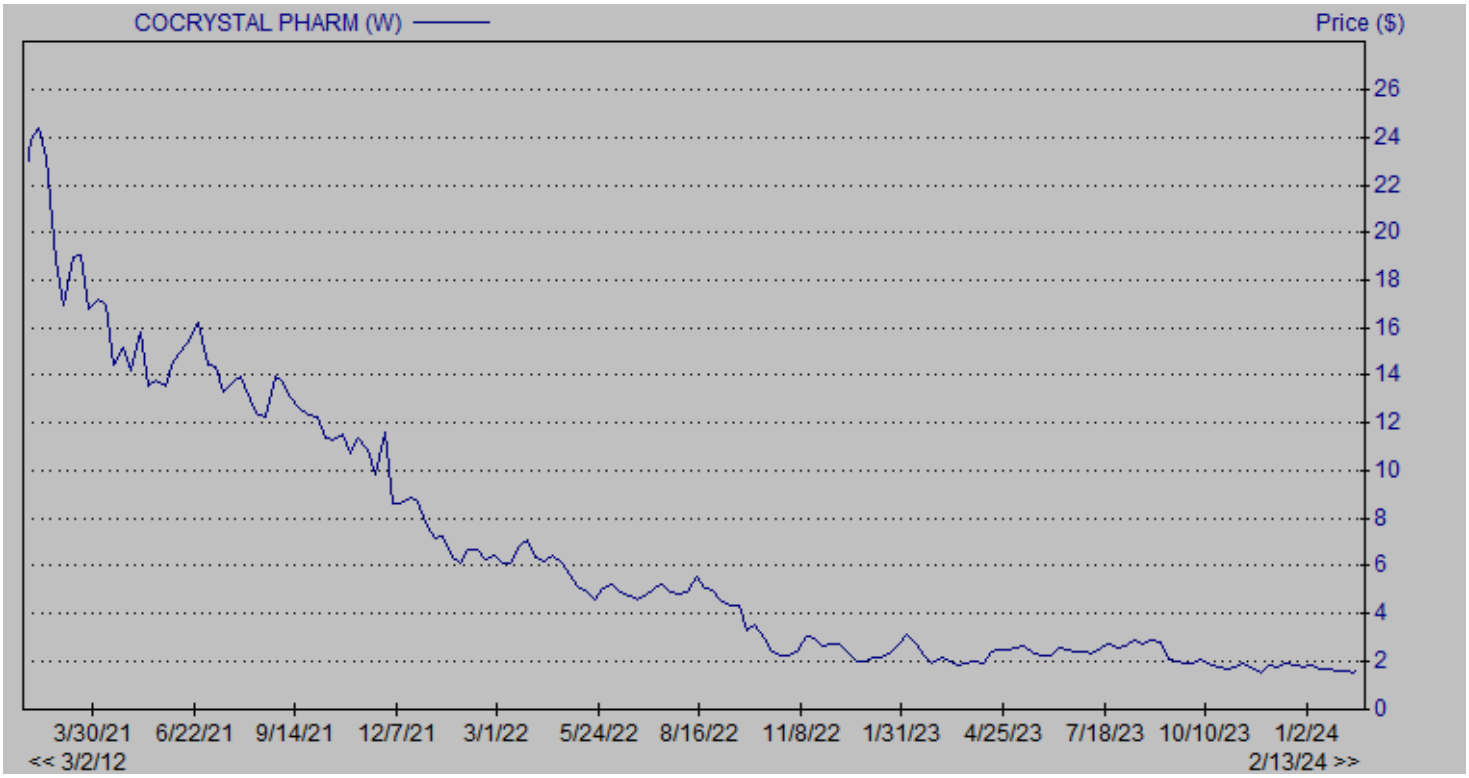
Source: cocrystalpharma.com/

PROJECTED INCOME STATEMENT

Income Statement	Dec-21	Dec-22	Dec-23	Dec-24	Dec-25
Net Sales	**0**	**0**	**0**	**0**	**2,000,000**
Growth	*-100.0%*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*
Cost of Goods Sold	**0**	**0**	**0**	**0**	**700,000**
%	*N/A*	*N/A*	*N/A*	*N/A*	*35.0%*
Depreciation & Amort	**0**	**0**	**0**	**0**	**0**
Gross Profit	**0**	**0**	**0**	**0**	**1,300,000**
Margin	*N/A*	*N/A*	*N/A*	*N/A*	*65.0%*
Sales & Marketing Expenses	**0**	**0**	**(1,600,000)**	**1,000,000**	**(20,000)**
% of sales	*N/A*	*N/A*	*N/A*	*N/A*	*-1.0%*
General & Administrative Expenses	**5,045,000**	**5,745,000**	**6,440,000**	**5,474,000**	**4,652,900**
% of sales	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*232.6%*
Research & Development	**8,794,000**	**12,392,000**	**14,902,000**	**14,156,900**	**13,802,978**
% of sales	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*690.1%*
Amortization	**382,000**	**0**	**0**	**0**	**0**
% of sales	*N/A*	*N/A*	*N/A*	*N/A*	*0.0%*
Operating Income	**(14,221,000)**	**(18,137,000)**	**(19,742,000)**	**(20,630,900)**	**(17,135,878)**
Margin	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*-856.8%*
EBITDA	**(13,839,000)**	**(18,137,000)**	**(19,742,000)**	**(20,630,900)**	**(17,135,878)**
Margin	*N/A*	*N/A*	*N/A*	*N/A*	*-856.8%*
Other Expenses/(Income)	**(40,000)**	**6,000**	**(651,000)**	**(44,353)**	**40,304**
%	*N/A*	*N/A*	*N/A*	*N/A*	*2.0%*
EBIT	**(14,181,000)**	**(18,143,000)**	**(19,091,000)**	**(20,586,547)**	**(17,176,181)**
%	*N/A*	*N/A*	*N/A*	*N/A*	*-858.8%*
Total Interest Exp (net)	**4,000**	**2,000**	**0**	**0**	**0**
%	*N/A*	*N/A*	*N/A*	*N/A*	*0.0%*
Net Profit Before Tax	**(14,185,000)**	**(18,145,000)**	**(19,091,000)**	**(20,586,547)**	**(17,176,181)**
%	*N/A*	*N/A*	*N/A*	*N/A*	*-858.8%*
Income Tax	**0**	**0**	**0**	**0**	**(2,576,427)**
% Effective Rate	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*15.0%*
% Cash Tax Rate	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*15.0%*
Minority Interests	**0**	**0**	**0**	**0**	**0**
Net Profit	**(14,185,000)**	**(18,145,000)**	**(19,091,000)**	**(20,586,547)**	**(14,599,754)**
%	*N/A*	*N/A*	*N/A*	*N/A*	*-730.0%*
Non-recurring income (expense)		(20,692,000)			
Average Diluted Shares Outstanding	7,364,000	8,143,000	9,500,000	10,065,000	10,065,000
Reported FD EPS		(4.09)			
Zacks Cash EPS	**(1.87)**	**(2.23)**	**(2.01)**	**(2.05)**	**(1.45)**
Zacks EPS	**(1.93)**	**(2.23)**	**(2.01)**	**(2.05)**	**(1.45)**

Source: Zacks analyst

HISTORICAL STOCK PRICE



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