Cocrystal Pharma

Jun 21, 2024

Cocrystal Updates Studies On Influenza and Bird Flu

Healthcare

COCP

NCM

Rating

Outperform

Unchanged

Current Price

\$2.55 Target Price

\$10.00

Market Capitalization 25.94M

Shares Outstanding 10.17M

Float **7.1M**

Institutional Holdings 7.09%

12-Month Low/High \$1.33/\$3.29

Average 90-Day Volume **30480**

Fiscal Year End 12/31/2024

2023E Period 2022A 2024E Q1 0.0 0.0A 0.0E Q2 0.0 0.0A 0.0E Q3 0.0 0.0A 0.0E 0.0F 0.0E 0.0 0.0E 0.0E 0.0 **EPS (\$)** 2025E Period 2023A 2024E Q1 (0.64)(0.39)A(0.44)EQ2 (0.42)E(0.46)E(0.41)Q3 (0.41)(0.42)E(0.48)EQ4 (0.43)E(0.48)E(0.66)(1.86)E(2.66)(1.67)E

Revenues (\$ MIL)

Potential Efficacy Against A New Strain Of Avian Influenza. Cocrystal has announced that studies of its influenza drug, CC-42344, have shown efficacy against the new avian influenza strain H5N1. Cocrystal has used its proprietary technology to determine the strain's mutations and structure, then conduct preliminary tests. The binding site for CC-42344 was not changed and can block reproduction of the new strain, making it an effective vaccine against the virus.

Avian Influenza Strain Has Begun To Infect Humans. Avian influenza H5N1 has caused significant illness in commercial bird flocks since 2003. Its impact was limited until recent outbreaks in dairy cattle and infections in diary workers. This ability to mutate and infect other species is a significant step toward causing widespread outbreaks in humans, elevating it to a public health concern.

CC-42344 Is In A Phase 2a Clinical Trial Cocrystal has been developing CC-42344 as a vaccine against influenza A, the type that causes illness in humans. It is an orally administered vaccine that targets PB2 of the virus, preventing the replication cycle in a broad spectrum of pandemic and seasonal influenza strains. The Phase 2a human challenge trial is currently in the follow-up period, having completed enrollment in May 2024. Data expected to be reported in 2H24. The company has received FDA guidance on the IND filing requirements for Phase 2b trials in the US, expected in 2H24.

First Clinical Trial For The Inhaled Version Of CC-42344 Is Planned. An inhaled version of CC-42344 is in development for post-exposure prophylactic treatment and therapeutic treatment for influenza A, with a GLP toxicology study in progress. Preclinical studies testing the inhaled version have shown superior pulmonary exposure. A Phase 1 is planned for 2H24 in Australia.

Conclusion. Development of CC-42344 has been based on inhibition the PB2 enzyme involved in the replication of the influenza virus, in contrast to the antibody vaccines. We believe the new studies show that CC-42344 maintains efficacy against H5N1, and supports earlier data showing efficacy against multiple strains of seasonal and pandemic influenza virus. This could become the universal flu vaccine that has been elusive for many years. We are reiterating our Outperform rating and \$10 price target.

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Refer to the last two pages for Analyst Certification & Disclosures

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Summary. Cocrystal announced studies of its influenza drug, CC-42344, have shown efficacy against the new avian influenza strain H5N1. This influenza strain has previously been limited to birds but has recently mutated to infect dairy cows and dairy workers, raising concerns about potential outbreaks.

Preclinical studies using Cocrystal's proprietary technology have determined the strain's mutations and structure. The binding site for CC-42344 is not affected by the mutations, and it retains potency against this new strain. This could become a new vaccine for avian influenza, and supports Cocrystal's strategy of developing drugs that inhibit enzymes that act early in the viral reproduction cycle.

Avian Influenza H5N1 Has Begun Infecting Humans. The H5N1 influenza strain has infected commercial bird flocks since 2003. It has recently necessitated euthanizing flocks of egg laying hens, causing economic damage to poultry production. The infection was not transmitted to other species and its impact was limited to increases in the price of eggs.

Recent Developments and Testing. On April 1, 2024, the CDC reported a case of highly pathogenic avian influenza A H5N1 in a farmworker in Texas. This was part of a multistate outbreak of avian influenza in dairy cows, with two more cases reported in farmworkers in Michigan. By early June, the CDC confirmed three cases of avian influenza infection from exposure to dairy cows and confirmed the spread to more than 100 dairy herds in 12 US states. These numbers may seem small, but the mutations that enable the virus to infect humans are a significant step toward causing widespread outbreaks in humans.

Current Influenza Vaccines Showed Little To No Protection. As part of its regular monitoring of influenza in the US, the CDC collected and stored blood samples from people in all age groups in each of the ten Health & Human Services regions during the 2022-2023 and 2021-2022 flu seasons. These samples were used to test the new avian H5N1 strain to determine if there was an antibody response, as strains with small changes can many have cross-reactivity from previous immune responses. These tests showed little to no immunity whether or not the individual had received a seasonal flu vaccination. This shows that new strain is significantly different from previous strains, and that prior vaccination does not give protection.

Cocrystal's Tests Revealed Several Genomic Mutations That Allow It To Infect Humans. In April 2024, the CDC published the genomic sequence of the avian influenza virus. Cocrystal was able to use this data with its proprietary crystallography technologies to construct a model for testing CC-42344.

The new H5N1 avian influenza virus contains several new mutations that have allowed it to jump from birds to humans. Importantly, these mutations are in regions away from the PB2 active site where CC-42344 binds. Preliminary in vitro assays show that CC-42344 retains its potent binding to the active site, making the vaccine a potential treatment against H5N1 avian influenza.

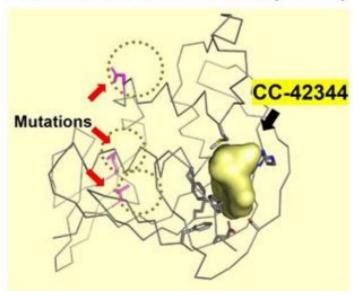
CC-42344 has shown highly potent antiviral activity against multiple influenza A strains, including pandemic and seasonal strains as well as against strains resistant to Tamiflu and Xofluza. We believe the new data supports development of CC-42344 as a vaccine that can be effective against multiple influenza strains, including H5N1.

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Exhibit 1. Changes To The Avian Influenza Virus Allow It To Infect Humans. Cocrystal was able to use its proprietary crystallography technologies to determine the crystal structure of the avian influenza A (H5N1). The study showed new mutations that are located away the PB2 active site. Preliminary in vitro assays show that CC-42344 binds to the active site of the avian influenza A (H5N1), as previously demonstrated with the pandemic and seasonal influenza A PB2. We believe this is consistent with the development of CC-42344 as a vaccine that can be effective against multiple influenza strains, including H5N1.

2024 Avian Influenza A (H5N1)



Source: Cocrystal Pharma, Inc.

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First Clinical Trial For The Inhaled Version Of CC-42344 Is Planned. As the oral version of CC-42344 is in Phase 2b, an inhaled version is in development for post-exposure prophylactic treatment and therapeutic treatment for influenza A, with a GLP toxicology study in progress. Preclinical studies testing the inhaled version have shown superior pulmonary exposure. A Phase 1 is planned for 2H24 in Australia.

Conclusion. Development of CC-42344 has been based on inhibition the PB2 enzyme involved in the replication of the influenza virus, in contrast to the vaccines that stimulate antibody responses. We believe the new H5N1 avian flu studies show that targeting PB2 maintains efficacy and could be effective against multiple strains of seasonal and pandemic influenza virus. This could become the universal flu vaccine that has been elusive for many years. We are reiterating our Outperform rating and \$10 price target.

Company Profile

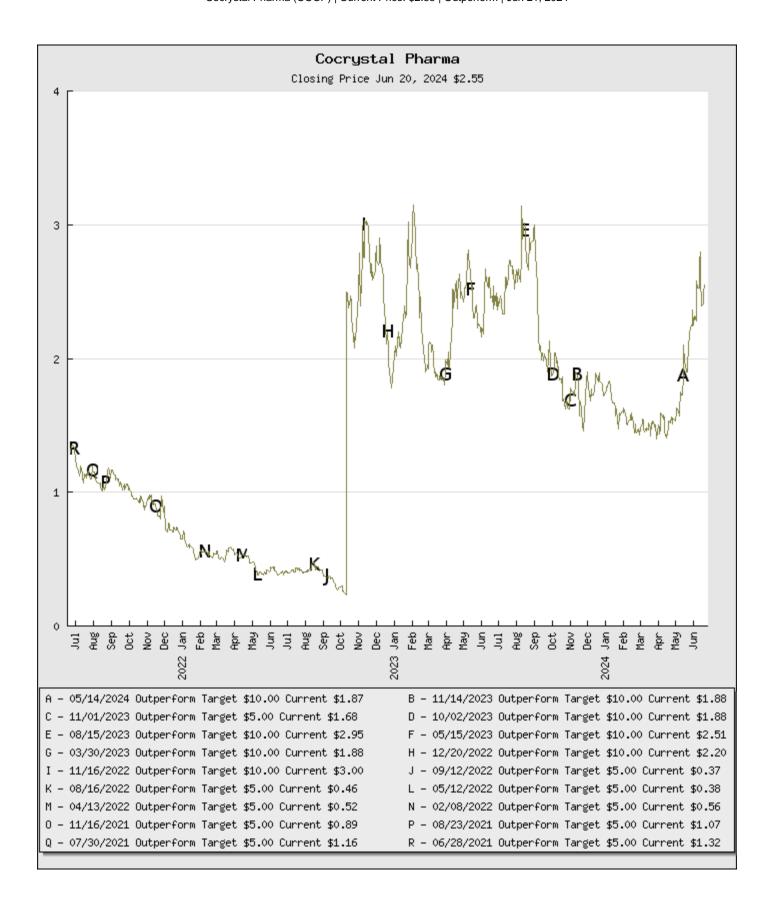
Cocrystal is a clinical-stage company focused on developing therapeutics for viral diseases. The company has developed a technology platform to treat hepatitis C virus (HCV), influenza, norovirus, and coronavirus infections. The most advanced product is CC-31244, a hepatitis C virus (HCV) non-nucleoside polymerase inhibitor. A polymerase basic protein 2 (PB2) inhibitor is in development trials for the treatment of influenza. Cocrystal has license agreements to develop antiviral compounds for the treatment of norovirus and coronavirus infections, and research collaboration agreement with Merck & Co to discover and develop proprietary influenza A/B antiviral agents.

Fundamental Analysis - 3.5/5.0 Checks

In our assessment, we give COCP 3.5 checks out of 5.0, which falls within our "Above Average" range of 3.5 to 4.0 checks. The company's executives and advisors are accomplished scientists with experience to guide development of anti-virals for indications with high unmet needs. For further explanation of our fundamental analysis, refer to the disclosures at the end of this report.

Valuation Summary

Cocrystal currently trades at a market valuation of about \$17.6 million, lower than its reported cash balance of \$21.8 million or \$2.14 per share on March 31, 2024. Our price target of \$10 per share is based on about 2X to 4X the cash balance, with little valuation for the products or the proprietary technology. Risks include; regulatory obstacles, clinical trial risk, and financial risks.



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The Company has attended Noble investor conference(s) in the last 12 months.

Noble intends to seek compensation for investment banking services and non-investment banking services (securities and non-securities related) within the next 3 months.

Noble is not a market maker in the Company.

FUNDAMENTAL ASSESSMENT

The fundamental assessment rating system is designed to provide insights on the company's fundamentals both on a macro level, which incorporates a company's market opportunity and competitive position, and on a micro/company specific level. The micro/company specific attributes include operating & financial leverage, and corporate governance/management. The number of check marks that a company receives is designed to provide a quick reference and easy determination of the company's fundamentals based upon the following five attributes of the company (weighting reflects the importance of each attribute in the overall scoring of company's fundamental analysis):

| Attribute | Weighting |
|---------------------------------|-----------|
| Corporate Governance/Management | 20% |
| Market Opportunity Analysis | 20% |
| Competitive Position | 20% |
| Operating Leverage | 20% |
| Financial Leverage | 20% |

For each attribute, the analysts score the company from a low of zero to a high of ten based upon the analysis described below. The final rating and resulting check marks is a result of dividing the overall score (out of 100%) by ten.

| Rating | Score | Checks |
|---------------|-----------|-----------------------|
| Superior | 9.1 to 10 | Five Checks |
| Superior | 8.1 to 9 | Four & A Half Checks |
| Above Average | 7.1 to 8 | Four Checks |
| Above Average | 6.1 to 7 | Three & A Half Checks |
| Average | 5.1 to 6 | Three Checks |
| Average | 4 to 5 | Two & A Half Checks |
| Below Average | 3 to 3.9 | Two Checks |
| Below Average | 2 to 2.9 | One & A Half Checks |
| Low Quality | 0 to 1.9 | One Check |

While these are the attributes currently used for the analyst's fundamental analysis, the attributes and weighting may be reviewed, updated with additional attributes, and/or changed in the future based on discussions with the analysts and recommendations from the Director of Research.

Following is the description of each attribute in the fundamental analysis.

Corporate Governance/Management

We believe that a review of corporate governance and assessment of the senior management are important tools to determine investment merit. Good corporate governance aligns management with the interests of stakeholders. As such, analysts are to rank the company on the basis of good corporate governance principles that may include rules and procedures, board composition and staggered term limits, rights and responsibilities, corporate objectives, monitoring of actions and policies, and accountability. In addition, analysts will assess issues with controlling shareholders and whether decisions have been made in the past that were in the interests of all shareholders. In addition, management will be assessed based on industry experience, expertise, and/or track record.

High ranking example: Board and management that is aligned with the interests of shareholders with incentives based on stock price appreciation and with an experienced management team known for exceptional shareholder returns.

Low ranking example: Concentrated ownership without independent directors that do not necessarily align with all shareholders' interests.

The Market Opportunity Analysis

In this review, the analyst assesses the company's macro environment as a measure of understanding the industry. Factors considered include the size and growth potential of the industry under various economic conditions, the emerging demands in the market, technological benefits/disruptions, competition, geographical opportunities, and customer demands/needs, and an assessment of supply and distribution channels. In addition, the analyst will review legal and regulatory trends, as well as potential shifts in consumer or social behavior and natural environment changes.

High rank example: A company in an industry that is growing revenues well above GDP rates (which are on average 2% plus) and/or may have unmet or underserved needs in a rapidly growing market opportunity.

Low rank example: A mature industry that is in secular decline and likely to grow below GDP rates.

Competitive Position

The evaluation of the company's competitive position is another macro environment attribute designed to measure the relevance, market share, position and value proposition, and sustainable differentiations of the company and its products/services within its industry. Ease of entry into the industry and the ability of other well-funded players to potentially enter the market would be determined. As such, the assessment would consider the company's strengths and advantages of its products/services against weaknesses and limitations. This may include the company's current brand awareness, pricing and cost structure, current market strategies and geographic penetration that may affect demand for its products/services. In addition, the company's competitors would be evaluated.

High rank example: An analyst would consider the company's product to be superior to its competitors and that should allow the company to gain market share.

Low rank example: A company with a "me-too" product that does not have any significant technology advantages in an industry that has low barriers to entry.

Operating Leverage

Simplistically, operating leverage is determined by the operating income relative to changes in revenue. The analyst will calculate the impact on sensitivity on gross margins and variable costs to determine operating leverage. The analyst will take into account the ability of the company to cut fixed and variable costs in a challenged revenue environment and technological changes that may impact operating expenses. In addition, the analyst is to assess corporate strategies that include capital investment, which may be required for sustainable revenue growth, marketing expenses, and the company's ability to attract and retain talent and/or employees. The analyst should focus on the revenue opportunity and determine the price elasticity of demand for the company's products or services. In other words, the analyst is to rank the company based on improved operating margins going forward on an absolute and relative basis.

High rank example: A company that has improving margins for the foreseeable future, with significant price elasticity.

Low rank example: A company that is in a challenged revenue environment with a fixed cost structure and limited ability to cut costs, indicating an outlook for declining margins.

Financial Leverage

A strict definition of financial leverage is total debt divided by total shareholder's equity. Financial leverage analysis is to determine the company's ability to improve shareholder value by means of utilizing its balance sheet to grow organically or to acquire assets. Analysts may look at the company's debt to cash flow leverage ratio, interest coverage ratios, or debt to equity ratios. In addition, the interest rate environment and the outlook for interest rates are a factor in determining the company's ability to manage financial leverage. Finally, the analyst is expected to determine the ability to service the debt given the industry and/or company profile, such as cyclicality, barriers to entry, history of bankruptcy, consistency in revenue and profit growth, or predictability in sales and profits and large cash reserves. The analyst is expected to take into account capital intensity of the company and the anticipated of capital allocation decisions.

High rank example: A company with predictable and growing revenue and cash flow with modest debt levels. This may indicate that the company could improve shareholder value through growth investments, including acquisitions, using debt financing.

Low rank example: A company in a cyclical industry in a late stage economic cycle that has above average debt leverage and is in an industry that has a history of financial challenges, including bankruptcies.

ANALYST CREDENTIALS, PROFESSIONAL DESIGNATIONS, AND EXPERIENCE

Senior Equity Research Analyst focusing on the Biotechnology and Specialty Pharmaceuticals industry. 16 years of industry experience. BA in Economics from Tulane University and an MBA from Columbia Business School. FINRA licenses 7, 24, 63, 86, 87

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Unless otherwise noted through the dropping of coverage or change in analyst, the analyst who wrote this research report will provide continuing coverage on this company through the publishing of research available through Noble Capital Market's distribution lists, website, third party distribution partners, and through Noble's affiliated website, channelchek.com.

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| NOBLE RATINGS DEFINITIONS | % OF SECURITIES COVERED | % IB CLIENTS |
|--|-------------------------|--------------|
| Outperform: potential return is >15% above the current price | 86% | 21% |
| Market Perform: potential return is -15% to 15% of the current price | 14% | 4% |
| Underperform: potential return is >15% below the current price | 0% | 0% |

NOTE: On August 20, 2018, Noble Capital Markets, Inc. changed the terminology of its ratings (as shown above) from "Buy" to "Outperform", from "Hold" to "Market Perform" and from "Sell" to "Underperform." The percentage relationships, as compared to current price (definitions), have remained the same.

Additional information is available upon request. The recipient of this report who wishes further information regarding the subject company or the disclosure information mentioned herein, should contact by mail or phone.

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