

**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): November 28, 2023

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

N/A

(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 (see General Instruction A.2. below):

- ☐ 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))

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>
<u>Common Stock</u>	<u>COCP</u>	<u>The Nasdaq Stock Market LLC (The Nasdaq Capital Market)</u>

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

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. ☐

Item 7.01 Regulation FD Disclosure.

On November 28, 2023, Sam Lee, President and Co-Chief Executive Officer of Cocrystal Pharma, Inc. (the "Company") is presenting at the World Vaccine Conference. A copy of the slide presentation is being furnished as Exhibit 99.1 to this Current Report on Form 8-K. The Company will also make available a webcast recording of the presentation on its website at www.cocrystalpharma.com beginning on November 29, 2023. In addition, on November 29, 2023 the Company issued a press release regarding the presentation and the Company's CC-42344 influenza A product candidate described therein, a copy of which is being furnished as Exhibit 99.2 to this Current Report on Form 8-K.

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.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Cocrystal Pharma, Inc. Corporate Presentation, dated November 28, 2023
99.2	Press Release dated November 29, 2023
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.

Dated: November 29, 2023

Cocrystal Pharma, Inc.

By: /s/ James Martin

Name: James Martin

Title: Chief Financial Officer and Co-Chief Executive Officer



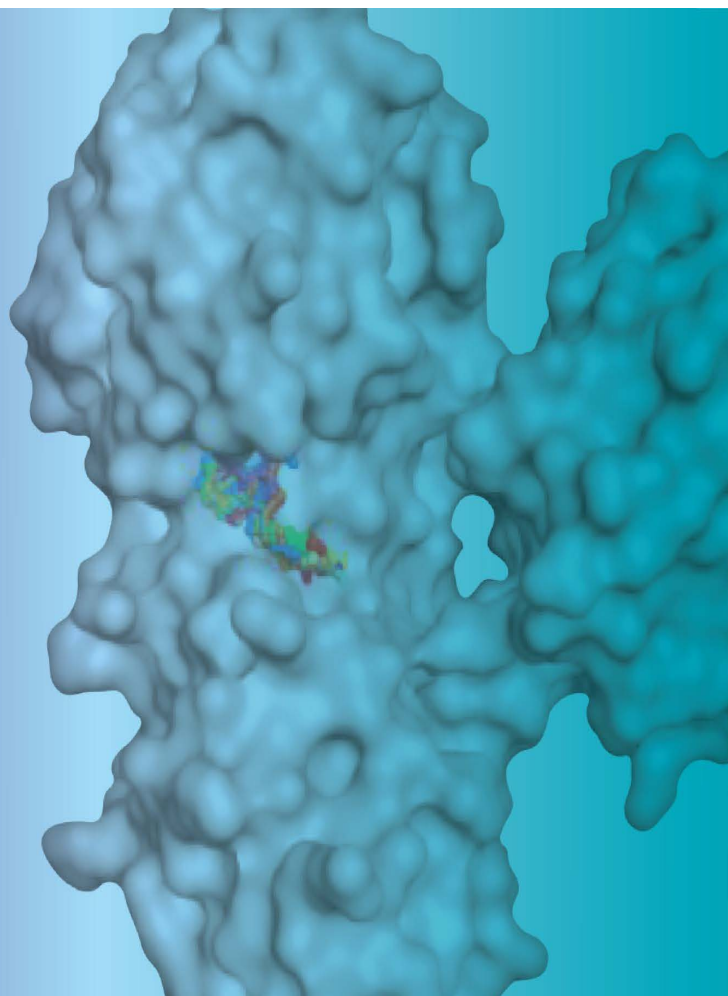
Taking a New Route:
Development of novel inhaled and oral
Polymerase PB2 Inhibitor, CC-42344

Sam Lee, Ph.D.

President & Co-CEO

World Vaccine Congress West Coast 2023

November 28 , 2023



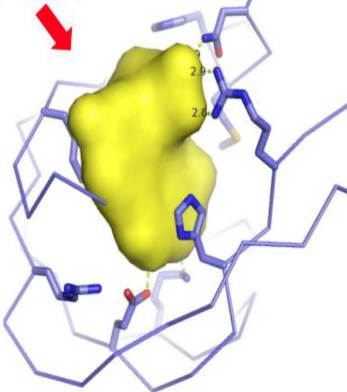
Forward-Looking Statements

This presentation contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements regarding the expected future characteristics and progress in our clinical programs, including our ongoing Phase 2a study for an oral influenza PB2 inhibitor, our anticipated initiation of a Phase 1 study for an inhaled influenza PB2 inhibitor in 2024, an an expected update in our influenza A/B program collaboration with Merck Sharp & Dohme Corp. ("Merck") in 2024.

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 our ability to proceed with studies including recruiting volunteers for and procuring or manufacturing materials for such studies by our clinical research organizations and vendors, the results of the Phase 2a and Phase 1 studies referred to above, the risk that Merck may cease to provide support for further development of the influenza A/B program under the license and collaboration agreement, 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, and potential mutations in the viruses we are targeting which may result in variants that are resistant to a product candidate we develop. 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, 2022. 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.

Influenza PB2

CC-42344

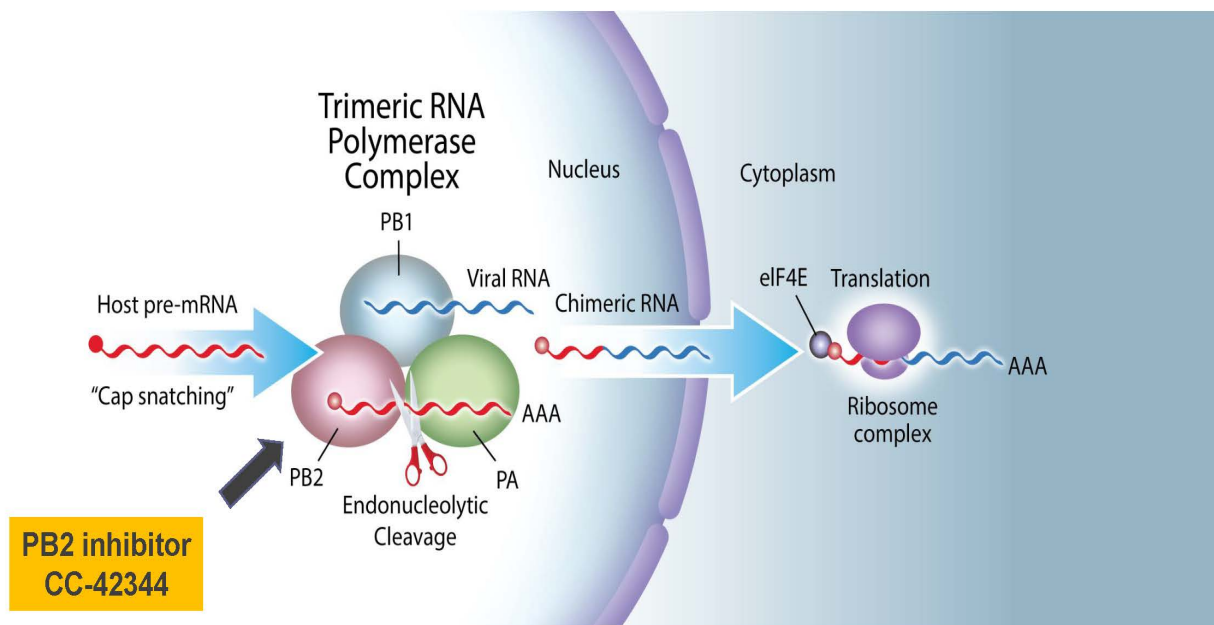


Cocrystal structure of CC-42344 (1.47 Å)

Properties of CC-42344

- Favorable safety profile
- Potent, broad-spectrum activity against pandemic and seasonal strains
- High barrier to resistance
- Superior pulmonary pharmacology: high exposure and a long half-life
- One molecule for therapeutics and prophylaxis
- Oral inhibitor: Phase 2a ongoing
- Inhaled inhibitor: Phase 1 planned in 2024

Mechanism of Action: CC-42344 Blocks The First Step of Influenza A Viral Replication

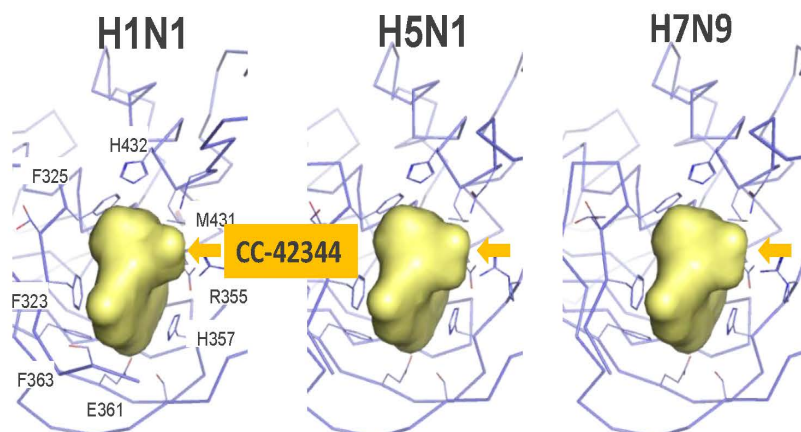


CC-42344 Binds to Highly Conserved Active Site of Influenza A PB2 Protein

Cocrystal proprietary drug discovery platform technology



Highly pathogenic influenza A strains

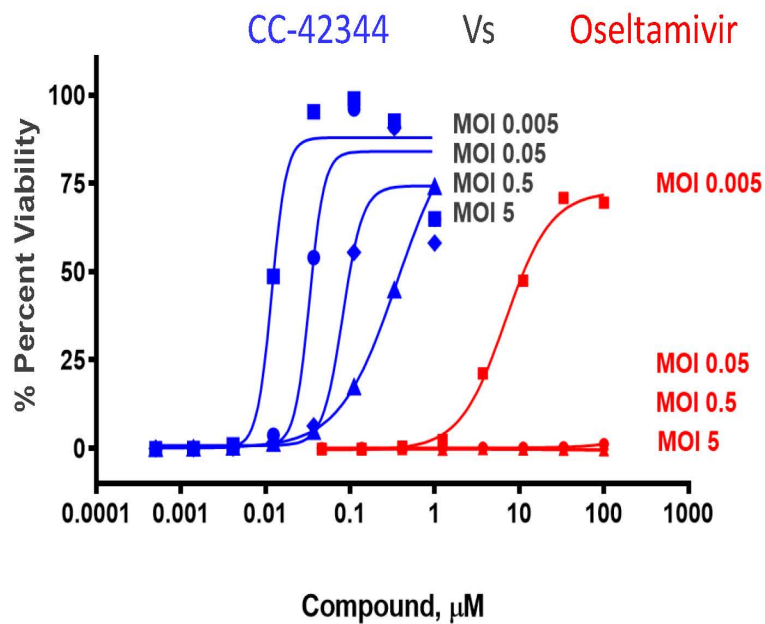


CC-42344 Shows Broad-spectrum Antiviral Activity Against Pandemic and Seasonal Influenza A Strains

Influenza Serotype	Strain	CC-42344 EC ₅₀ (nM)
H1N1	A/PR/8/34	1
Pandemic H1N1	California/04/2009	0.5
H1N1	A1/Denver/1/57	3
H1N1	A/Fort Monmouth/1/47	2
H1N1	A/NY/18/09	5
H3N2	A/AICHI/2/68	0.2
Highly pathogenic Avian H5N1	Duck/MN/1524/81	<3.2
Highly pathogenic Avian H5N1	Hong Kong/213/2003	4.5
Highly pathogenic Avian H5N1	Thailand/16/2004	<3.2
Highly pathogenic Avian H7N7	Netherlands/219/2013	5.6
Highly pathogenic Avian H7N9	Anhui/1/2013	<3.2
H1N1- Oseltamivir resistant	A/HK/2369/09 H274Y	9
H3N2-Oseltamivir resistant	A/Wuhan/395/95	0.5
H1N1- Baloxavir resistant (I38T)	A/PR/8/34 I38T	0.5

CC-42344 Exhibits Superior Antiviral Activity Compared to Oseltamivir

CC-42344 exhibits superior antiviral activity at higher MOIs (multiplicity of infection)



Cocrystal Structure-Based Drug Discovery Platform Technology Delivers Multiple Broad-Spectrum Antiviral Leads, Influenza and Others

Cocrystal technology uniquely offers:

- 1 Systematic analysis of drug binding pockets for broad-spectrum antivirals
- 2 Rapid crystal structure determination and computational drug design
- 3 Structural insight into antiviral drug resistance
- 4 Novel clinical drug candidates

Program	Candidate	Discovery	Preclinical	Phase 1	Phase 2	Phase 3
Influenza	Oral PB2 inhibitor CC-42344					Phase 2a ongoing
	Inhaled PB2 inhibitor CC-42344					Phase 1 planned H1 2024
	Influenza A/B inhibitor					Collaboration updated Expected H1 2024
	Replication inhibitor					

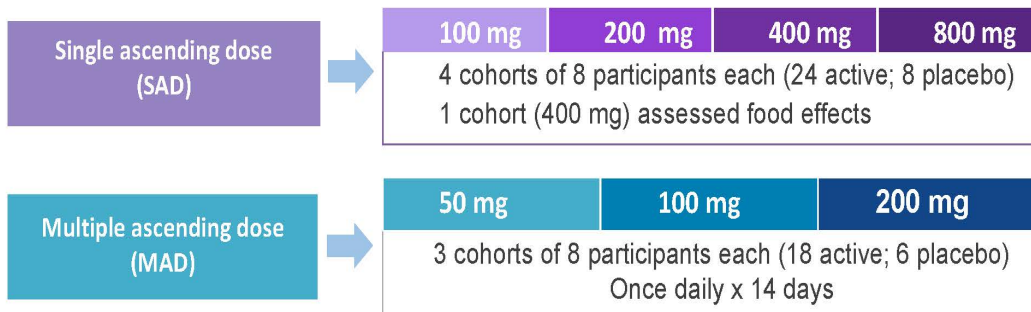


Oral CC-42344: Phase 1 Data Demonstrates Favorable Safety Profile, Advancing to Phase 2a

Phase 1 site: Linear Clinical Research – Harry Perkins Research Institute, Perth, Australia

Participants:

- Single-center, randomized, double-blind, placebo-controlled
- Single-ascending dose, multiple-ascending dose; 7-day nontreatment follow-up period
- Healthy adult volunteers
- Each cohort comprised of 8 subjects; 6, CC-42344 and 2, placebo
- N = 56; 32, SAD; 24, MAD



Endpoints

- Adverse events (AEs), physical exam, viral signs, ECGs, and lab indices
- Food effect

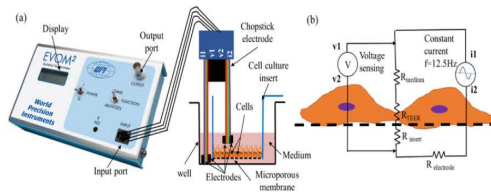


Advantages of inhalation antiviral therapy

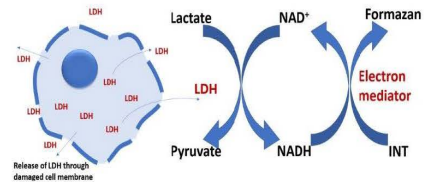
- Directly targets infected respiratory epithelial cells
- Achieves higher accumulation of drug in the pulmonary system
- Produces rapid clinical response
- Reduces potential systemic side effects

Evaluating Toxicity in In Vitro Human Upper Airway Epithelium

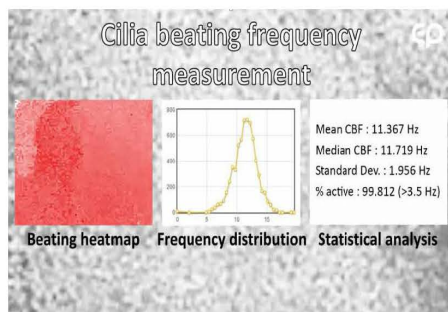
(A) Trans-epithelial electrical resistance determination



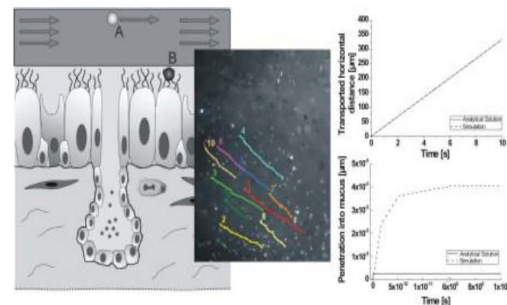
(B) Lactate dehydrogenase



(C) Cilia beating frequency determination

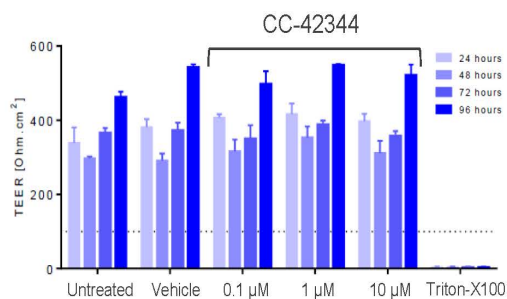


(D) Mucociliary clearance determination

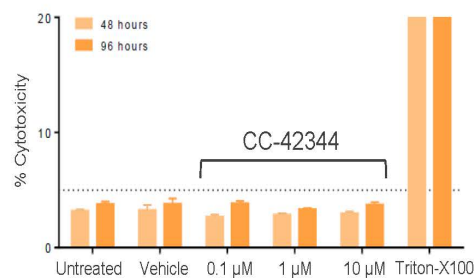


CC-42344 Showed Favorable Safety Profile in Human Upper Airway Epithelium

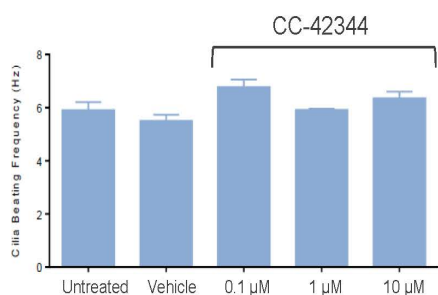
(A) Trans-epithelial electrical resistance determination



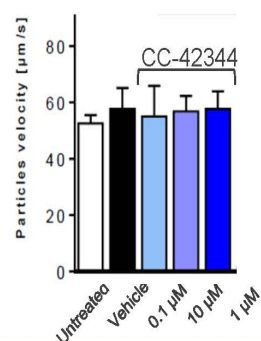
(B) Lactate dehydrogenase



(C) Cilia beating frequency determination



(D) Mucocilliary clearance determination



CRYSTAL
PHARMA, INC.

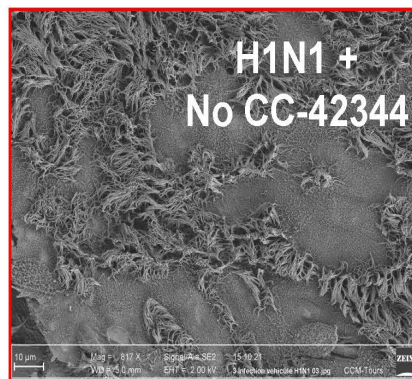
CC-42344 Shows Excellent Antiviral Activity in Influenza H1N1-Infected Human Upper Airway Epithelium

Uninfected human upper airway epithelia
by scanning electron microscopy

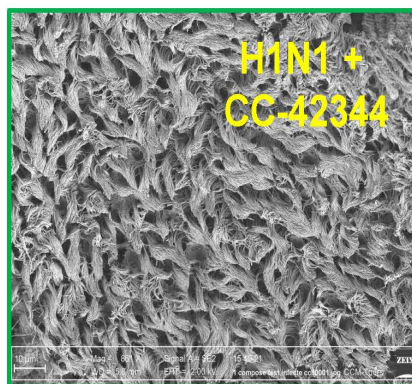


+ H1N1

No
treatment

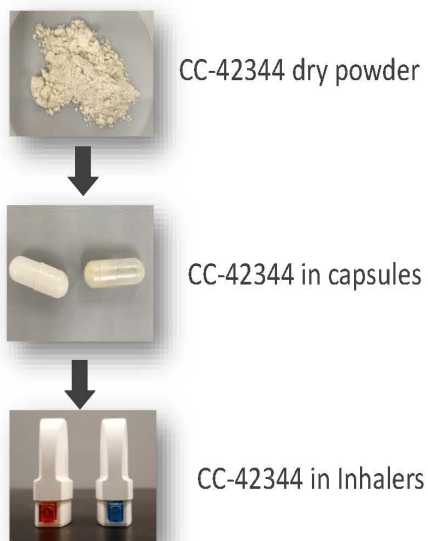


With
CC-42344

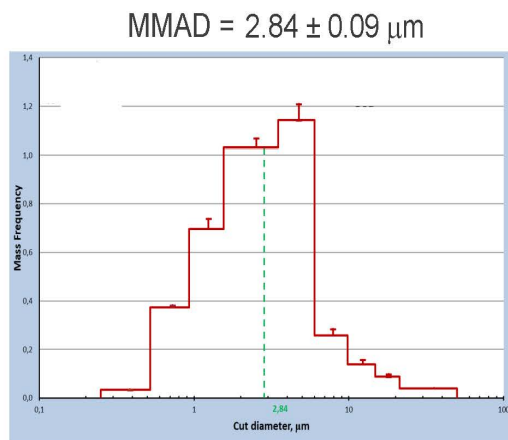


Oral Inhalation Formulation Development Completed

(A) Prototype dry powder manufacturing

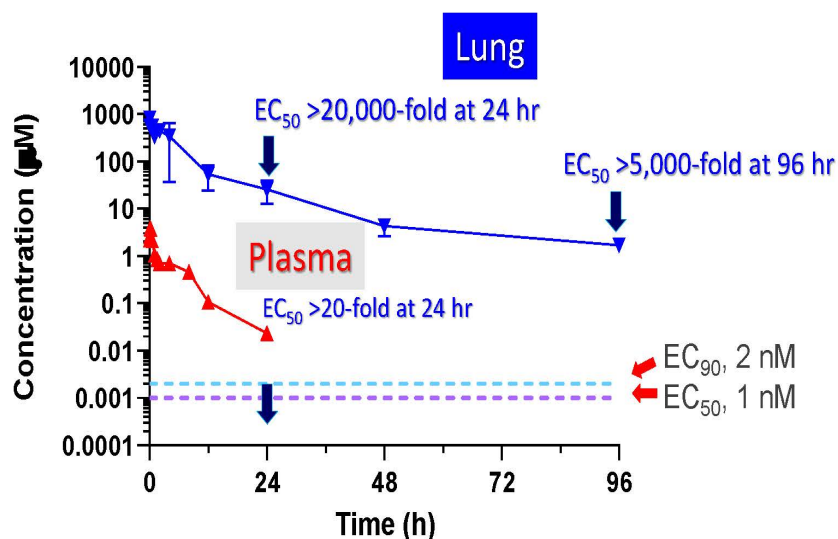


(B) Aerodynamic particle size distribution



Inhaled CC-42344: Potential Prophylactic and Therapeutic Treatment

Inhaled CC-42344 achieves high exposure in lung



Mouse pharmacokinetic profile of CC-42344 dry powder (5 mg/kg),
single intratracheal administration

CC-42344 In an Inhaler Device Showed Excellent Dissolution and Absorption Rates Using Precise Inhale Aerosol Generator and DissolvIt®

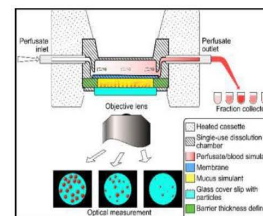
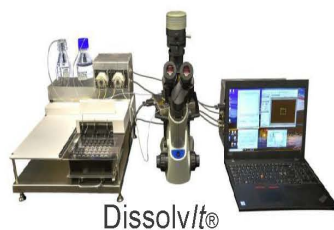
Precise Inhale aerosol generator (Inhalation Sciences)



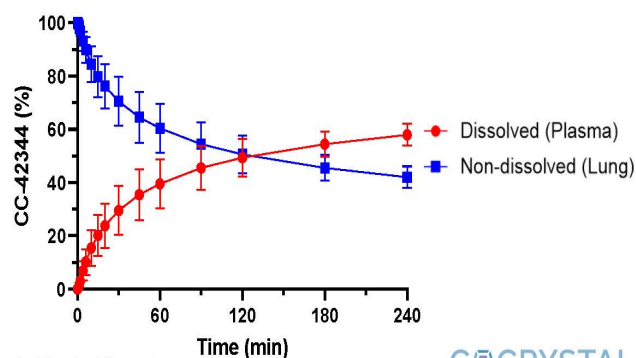
CC-42344



CC-42344



Simulated PK profile of CC-42344



SUMMARY

- Favorable safety profile
- Potent, broad-spectrum activity against pandemic and seasonal strains
- High barrier to resistance
- Superior pulmonary pharmacology: high exposure and long half-life, EC_{50} >5,000-fold at 96 hr after single administration
- Oral CC-42344: Phase 2a ongoing
- Inhaled CC-42344: Phase 1 planned in 2024



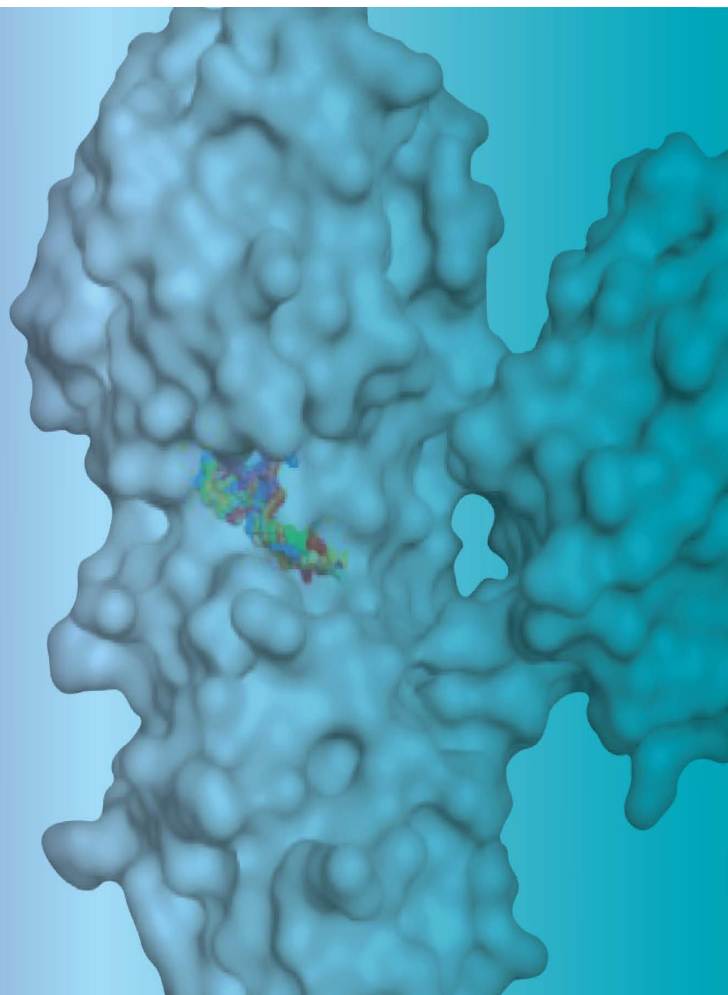
Taking a New Route:
Development of novel inhaled and oral
Polymerase PB2 Inhibitor, CC-42344

Sam Lee, Ph.D.

President & Co-CEO

World Vaccine Congress West Coast 2023

November 28 , 2023





Cocrystal Pharma Highlights its Novel Inhaled and Oral Influenza A Antiviral CC-42344 at the World Vaccine Congress West Coast

BOTHELL, Wash. (November 29, 2023) – Cocrystal Pharma, Inc. (Nasdaq: COCP) (“Cocrystal” or the “Company”), announces the presentation of favorable data demonstrating activity of its potent broad-spectrum PB2 inhibitor CC-42344 against pandemic and seasonal influenza A strains at the World Vaccine Congress West Coast. Cocrystal has initiated a Phase 2a human challenge trial with oral CC-42344 in the UK in subjects infected with influenza A, and plans to begin a Phase 1 trial with inhaled CC-42344 as a potential influenza A treatment and prophylaxis in Australia in the first half of 2024

In his presentation, “*Taking a new route: Development of novel inhaled and oral influenza antiviral, CC-42344*,” Cocrystal President and co-CEO Sam Lee, PhD discussed the potential prevention and therapy of influenza infection using inhaled CC-42344. Dr. Lee commented that CC-42344 exhibits superior antiviral activity compared with oseltamivir (Tamiflu®) and demonstrates a novel mechanism of action with high barrier of resistance. He noted that Cocrystal discovered and developed CC-42344 utilizing the Company’s proprietary structure-based drug discovery platform technology, which is proving successful in delivering multiple broad-spectrum antiviral leads for influenza and other viral diseases.

“We are excited to accomplish another important milestone with the influenza antiviral CC-42344. Based on our recent preclinical data, CC-42344 exhibits superior lung exposure, a favorable safety profile, and efficacy in influenza-infected human lung epithelia. We also demonstrated highly efficient delivery of inhaled CC-42344 into the lung,” he said. “Inhaled CC-42344 could be developed for both therapeutic and prophylactic influenza treatment. We are encouraged by this potential breakthrough influenza treatment option.”

Slides from the presentation are available on the Company’s [website](#).

About CC-42344

CC-42344 is specifically designed to be effective against all significant pandemic and seasonal influenza A strains and to have a high barrier to resistance due to the way the virus’ replication machinery is targeted. CC-42344 targets the influenza polymerase, an essential replication enzyme with several highly essential regions common to multiple influenza strains. *In vitro* testing showed CC-42344’s excellent antiviral activity against influenza A strains, including pandemic and seasonal strains, as well as against strains resistant to certain approved influenza antivirals, while also demonstrating favorable pharmacokinetic and safety profiles.

About Seasonal Influenza

Each year there are approximately 1 billion cases of seasonal influenza worldwide, 3-5 million severe illnesses and up to 650,000 deaths, according to the World Health Organization. On average about 8% of the U.S. population contracts influenza each season. Influenza is responsible for approximately \$10.4 billion in direct costs for hospitalizations and outpatient visits for adults in the U.S. annually.

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) noroviruses and hepatitis C viruses. 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.

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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 the Company’s ongoing Phase 2a human challenge trial for CC-42344 as a product candidate for oral treatment of influenza A, and the planned initiation of a Phase 1 clinical trial in the first half of 2024 for CC-42344 as a product candidate for inhaled treatment of influenza A, and the potential efficacy and clinical benefits of, and market for, such product candidate. 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, risks relating to our ability to proceed with the Phase 2a and Phase 1 studies referred to above including recruiting volunteers for and procuring or manufacturing materials for such studies by our clinical research organizations and vendors, and the results of such studies. 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, 2022. 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.

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