

**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 15, 2023

Cocrystal Pharma, Inc.

(Exact name of registrant as specified in its charter)

Delaware (State or other Jurisdiction of Incorporation)	001-38418 (Commission File Number)	35-2528215 (IRS Employer Identification No.)
19805 N. Creek Parkway Bothell, WA (Address of principal executive offices)		98011 (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 7.01 Regulation FD Disclosure

Beginning on March 15, 2023, Cocrystal Pharma, Inc. (the "Company") published on its website and disseminated via certain online channels a recorded interview of Dr. Sam Lee, the Company's Co-Chief Executive Officer, in which Dr. Lee describes certain information concerning the Company's influenza, HCV and COVID-19 programs and its drug development platform, as well as developments in the biopharmaceutical industry generally. A copy of the transcript of this interview is being furnished as Exhibit 99.1 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

(d) Exhibits

Exhibit	Description
99.1	Transcript of Interview with Dr. Sam Lee, Co-Chief Executive Officer of Cocrystal Pharma, Inc.
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 15, 2023

By: /s/ James Martin

Name: James Martin

Title: Chief Financial Officer and Co-Chief Executive Officer

**Cross-Spectrum Anti-Viral Compounds Needed
for Seasonal and Pandemic Infections
with Sam Lee Cocrystal Pharma
An Empowered Patient Podcast Published March 15, 2023**

Karen Jagoda: Welcome to the EmpoweredPatientPodcast.com show. I'm Karen Jagoda, and my guest today is Sam Lee. He's the Co-CEO and President of Cocrystal Pharma, CocrystalPharma.com. Sam, I want to welcome you back to the show. It's been about a year since we talked, and it's great to have a chance to talk with you again.

Sam Lee: Thank you, Karen. Thanks for having me.

Karen Jagoda: This winter, we have seen three different virus outbreaks, RSV, COVID, and influenza. My first question is, what can you tell us about the differences between those three kinds of viruses?

Sam Lee: RSV and COVID, and flu they're caused by RNA viruses. These viruses also infect the human lungs. It could be the upper or lower airways of the lungs and sometimes intranasal epithelial cells. I want to point out that COVID and the influenzas are pandemic and seasonal issues, and RSV is not a pandemic virus. It is a seasonal virus, particularly the high-risk pediatric populations. And there is a drug for RSV, a prophylactic antibody drug, and it's widely used for these high-risk populations.

Karen Jagoda: Are people getting infected with more than one of these viruses during this season?

Sam Lee: Yes, there are lots of papers out there describing coinfection, particularly COVID and influenza. Based on publication, some infections could go up to 48%, coinfection. So this is a serious issue. These patients are when you have a COVID positive on top of the influenza. So you have a really serious lung issue. It's a really interesting topic to follow up on.

Karen Jagoda: We really have not heard very much about that topic. Is it the people who have COVID that are getting the flu, or are the people with flu now more vulnerable to COVID? Or is it hard to pull those two things apart?

Sam Lee: Good question. Studies that they've done start with the COVID-positive patients, then investigate whether they have influenza infections. Once again, in the United States, a lower coinfection rate compared to other parts of worldwide. Asians, average is somewhere around 4% coinfection, the United States is a lot lower. But again, it depends on the study subjects. There are some publications that they show up to 48% coinfection. It's a high coinfection rate.

Karen Jagoda: And that's 48% of the COVID people also show signs of having the flu. Is that correct?

Sam Lee: That's correct.

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- Karen Jagoda: There must be some unmet medical needs when they have these comorbidities that need to be addressed more effectively. Tell us a little about how doctors treat those kinds of patients.
- Sam Lee: With influenza, even though we have seasonal vaccines this year and last year, the effectiveness of the seasonal vaccines is not so great. That's probably part of the reason that we have a higher influenza infection rate. For influenza patients the standard care is the oral drug Tamiflu, and you have to treat the patient as early as possible, ideally less than 48 hours after influenza infection. So you have to have a timing, early infection, and symptom, then the clinician can provide the oral drug. And COVID, as we know, there are approved drugs. There are protease inhibitors as well as nucleoside inhibitors. They could treat the patients with the COVID drug. So there are available antiviral drugs for these, COVID as well as influenza.
- Karen Jagoda: But at the same time, you don't just want to treat those symptoms without realizing what you're treating. Tell us a little about how doctors determine the best treatment procedure for patients with those kinds of comorbidities.
- Sam Lee: I'm not an infectious disease clinician, but as far as I know, diagnostics for COVID and influenza's very straightforward, very sensitive. They can identify the infection. Once they have that information, they will treat, I assume, all together. So there are no drug-drug interaction concerns between these two drugs, protease inhibitors, Tamiflu. So I'll assume that the co-treatment would be available.
- Karen Jagoda: Thanks for clarifying that. The last time you were on, you talked about your influenza program. Give us an update on that.
- Sam Lee: We just completed the Phase I study. In the Phase I study, we demonstrated the favorable safety and tolerability of this compound, CC-42344. We designed this compound for pandemic and seasonal influenza A infection. Particularly, this compound is highly sensitive to the avian influenza strain, potentially an emerging pandemic strain. Our plan is to initiate the Phase IIa study. We'll be doing human challenge influenza trials. This would be we recruit healthy volunteers, and then we infect with the influenza A virus, and then we treat them with our drug. So it'd be clean endpoints and well controlled studies.
- Karen Jagoda: Tell us a little more about your drug development platform and what makes it unique.

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- Sam Lee: I think with antiviral drug development, you always have to think about three important things. One is the cross-spectrum, which covers the existing viruses. For example, in the influenza case, influenza H1N1, H2, and H3. And beyond seasonal influenza viruses are pandemic viruses, H5 and H7, and potentially emerging avian flu. So we want to cover all these viruses. That's a really important goal.
- Sam Lee: Once you achieve good potency and cross-spectrum activity, then you want to solve the pharmacology. It's going to be a once-a-day drug with the excellent drug resistance. Drug resistance is a really key contribution using our platform approach. Often, you have drug resistance issues. Drug resistance is a part of the survival mechanism for all RNA, DNA viruses. They will figure it out. If you treat them with some drug, it doesn't matter it's a small molecule, antiviral, or proteins. The virus will figure out how it could mutate the genes so they could develop resistance. Their goal is that they want to replicate their genomes in the host cell. But it's a selection process.
- Sam Lee: So, in the Tamiflu case, the circulating influenza virus, more than 10% of influenza virus is actually resistant to Tamiflu. The more we use it, we will see more resistance will pop up. In the COVID case, the early generation of antibody drugs that targeted the COVID protein, in fact, that single mutation could cause the problem, and you lose the efficacy. So, drug resistance is the key issue outside the cross-spectrum activity.
- Sam Lee: At Cocrystal, we spend a lot of time trying to figure out what we call identify drug pocket. Which pocket will give us cross-spectrum as well as how to prevent drug resistance? I think we've done really well. The first example would be HCV drug. We complete the Phase II study. Our compound's not only cross-spectrum, it has the high barrier to drug resistance. So, in fact, we were not able to isolate the drug-resistant HCV viruses after a long period of treatment. Our second molecule is the influenza compound 42344. We tried to isolate the drug-resistant viruses for several months, and we could not isolate the mutant viruses. So this is a really important property of a compound for the treatment of seasonal as well as pandemic strains.
- Sam Lee: Finally, in the antiviral compounds, ideally you want to have the combination therapy option. So there should be no drug-drug interactions, so you can combine our drug with the Tamiflu or baloxavir, any of these compounds could be useful. Then we'll have more options in case anything pops up. Then you could have an option for those newly emerging viruses. Our platform solves these several problems, cross-spectrum issues as well as drug resistance, and the potency, finally, the combination treatment options.

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- Karen Jagoda: That's an excellent overview. I was hoping you could just give us a little more detail about how you can predict the new mutations. I understand that these viruses go through cycles, so we might see 50 years later some mutation that we recognize. Can you say a little more about how accurately we can predict what will happen in the future based on what we know about the past?
- Sam Lee: It's really difficult to predict mutation's site, and mutation where it's going to happen, and what kind of phenotypes we're going to get. I'll give you one example. Baloxavir, this is the drug known as Xofluza. This is a compound that was approved in 2018. It's a really great influenza drug versus influenza A and B. The rate of brand-new resistance actually came out of this Phase IIa study. This drug, the pharmacology's really great. One pill for three months. So if you take one pill for influenza infection, it's really that you actually could cure influenza infection, in contrast with Tamiflu, a twice-a-day, five-day treatment.
- Sam Lee: However, baloxavir, when you take one pill, based on Phase IIa data, roughly 10% of patients experience resistance against the drug. So, one pill. So when you look at the drug resistance of this brand-new resistance against the baloxavir, it's not naturally occurring drug resistance. In other words, it's a new resistant influenza virus that's coming out of treated patients. So that's a concern. We've seen with Delta, Omicron, and other coronaviruses how rapidly virus can mutate.
- Sam Lee: What we're trying to do is that using computational data, as well as high-resolution X-ray data. We combine all our knowledge and try to predict if we can find the area the virus could have a problem to mutate. We're targeting a highly conserved region of the drug-binding pocket. So, then we have to increase the affinity of the drug so we can prevent the drug resistance. A critical component of the replication, you block that essential step, then actually the virus does not have a choice. It just gets killed.
- Sam Lee: So 42344, for example, we target the first step, we call PV2 protein, that actually is the essential process and very first step. We block the step with the multiple mechanisms of action. As a result, our prediction was correct that the compounds treated drug-resistant cells. We do not see drug-resistant viruses at this point.
- Karen Jagoda: My last question before we run out of time today is, what is the most significant milestone ahead for you in 2023?

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- Sam Lee: Yes, we'd like to complete the influenza 42344 Phase IIa study. We'll demonstrate the safety, as well as human antiviral efficacy. That's a really important milestone for our influenza program. Also, we want to move forward with the Merck collaboration, influenza A/B program. Merck's developing the clinical candidates. That's a second important milestone. The third important milestone is the COVID Phase I trial. We're really excited about our compound's protease inhibitor against COVID, and there will be a Phase I study in Australia. We look forward to completing the Phase I study.
- Karen Jagoda: Do you get the sense that we've learned some serious lessons from experience dealing with COVID the last few years that really make us better prepared to handle the next contagious outbreak?
- Sam Lee: Great question. I think we learn a lot from the COVID-19 pandemic. We really have to think about cross-spectrum antiviral compounds against potential pandemic viral infections. These are reasonably well characterized. If you recall SARS 1 back in 2002/2003, SARS 1 was a pandemic outbreak, and we did not develop the drug against SARS 1. And then after that, the MERS coronavirus infection, a very similar virus. Again, we did not have an antiviral drug, as well as the SARS 1. Now we have COVID-19-related coronaviruses, but it's caused serious pandemic issues. So, I think antiviral drug development is important. We have a potential pandemic antiviral target, for example, coronavirus, influenza, and other RNA viruses. We want to have cross-spectrum compounds ready for any pandemic outbreaks.
- Karen Jagoda: Thanks to my guest today, Sam Lee, Co-CEO and President of Cocrystal Pharma, CocrystalPharma.com. Follow them on Twitter @CocrystalPharma. I'm Karen Jagoda, and you've been listening to the EmpoweredPatientPodcast.com show. Follow me on Twitter @KarenJagoda. Like us on Facebook @EmpoweredPatientRadio. Thanks for listening, and we'll see you next time.



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