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): April 5, 2021

Cidara Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-36912**	**46-1537286**
(State or Other Jurisdiction of Incorporation or Organization)	**(Commission File Number)**	**(I.R.S. Employer Identification Number)**

6310 Nancy Ridge Drive, Suite 101
San Diego, California 92121
(858) 752-6170
(Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrant's Principal Executive Offices)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligations 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))

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, Par Value $0.0001 Per Share	**CDTX**	**The Nasdaq Global Market**

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 8.01 Other Events.

On April 5, 2021, Cidara Therapeutics, Inc. (the "Company") held a conference call to discuss the Company's previously announced exclusive worldwide license and collaboration agreement with Janssen Pharmaceuticals, Inc. The conference call transcript is attached hereto as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Transcript of Cidara Therapeutics conference call, held April 5, 2021.
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.

Cidara Therapeutics, Inc.

Date: April 5, 2021

/s/ Jeffrey L. Stein
Jeffrey L. Stein
President and Chief Executive Officer
(Principal Executive Officer)

Cidara Therapeutics – Cidara Therapeutics/Janssen Pharmaceuticals Collaboration Business Update, April 5, 2021

CORPORATE PARTICIPANTS

Tracey Sebastian, *LifeSci Advisors*

Jeff Stein, *President and Chief Executive Officer*

Jamie Levine, *Chief Financial Officer*

Paul Daruwala, *Chief Operating Officer*

CONFERENCE CALL PARTICIPANTS

Louise Chen, *Cantor Fitzgerald*

Joseph Stringer, *Needham & Company*

Nathan Weinstein, *Aegis Capital*

Robert Driscoll, *Wedbush Securities*

PRESENTATION

Operator

Good morning, ladies and gentlemen, and welcome to the Cidara Therapeutics Business Update Call.

At this time, all participants are in a listen-only mode. A brief question-and-answer session will follow the formal presentation. If anyone should require Operator assistance during the conference, please press star, zero on your telephone keypad. As a reminder, this conference is being recorded.

It is now my pleasure to introduce your host Tracey Sebastian with LifeSci Advisors. Thank you, Ms. Sebastian. You may begin.

Tracey Sebastian

Thank you, Operator, and thank you all for joining us today.

With me on today's call are Jeff Stein, President and Chief Executive Officer; Jamie Levine, Chief Financial Officer; and Paul Daruwala, Chief Operating Officer of Cidara Therapeutics.

This morning, Cidara issued a news release announcing that it has entered into a collaboration agreement with Janssen Pharmaceuticals, Inc., one of the Janssen Pharmaceutical Companies of Johnson & Johnson, to develop and commercialize Cidara's Cloudbreak antiviral conjugates, or AVCs, for the prevention and treatment of seasonal and pandemic influenza. The collaboration agreement was facilitated by Johnson & Johnson Innovation. Please note, the effectiveness of this agreement is subject to the expiration or earlier termination of all applicable waiting periods under the Hart-Scott-Rodino Antitrust Improvements Act.

Before I turn the call over to Jeff, I would like to note that all of the information discussed on the call today is covered under the Safe Harbor provisions of the Private Securities Litigation Reform Act. I caution listeners that during this call Management will be making forward-looking statements. Actual results could differ materially from those stated or implied by forward-looking statements due to risks and uncertainties associated with the Company's business. These forward-looking statements are qualified in their entirety by the cautionary statements contained in Cidara's SEC filings, including its Annual Report on Form 10-K.

I would also like to point out that the content of this conference call contains time-sensitive information that is accurate only as of the date of this live broadcast, April 5, 2021. Cidara undertakes no obligation to revise or update any forward-looking statements to reflect events or circumstances after the date of this conference call.

I will now turn the call over to Jeff Stein, President and CEO of Cidara.

Jeff Stein

Good morning everyone, and thank you for joining our call.

We are very excited to announce today that we have entered into an exclusive worldwide license and collaboration agreement with Janssen Pharmaceuticals, a part of Johnson & Johnson, to develop and commercialize Cidara's Cloudbreak Antiviral Conjugates, or AVCs, for the prevention and treatment of seasonal and pandemic influenza.

Our Cloudbreak antiviral platform represents a potentially transformational approach to prevent and treat viral infections, from which we are creating a new generation of immunotherapeutic antiviral conjugates for influenza, RSV, HIV, SARS-CoV2 and other viruses. AVCs are a novel class of drugs that couple potent antivirals to a human antibody fragment, or Fc. These long-acting AVCs directly inhibit viral replication while simultaneously engaging the immune system, and may offer significant advantages over vaccines and monoclonal antibodies. Our Influenza AVCs, such as CD388, are designed for rapid onset and have the potential to deliver potent universal flu protection for an entire flu season with a single dose.

Under the terms of the agreement with Janssen, Cidara will be responsible for the development and key aspects of manufacturing of our lead influenza AVC, CD388, into the clinic and through the first Phase 2 clinical trial, and Janssen will be responsible for and will fund late-stage development, manufacturing, registration, and worldwide commercialization. Janssen will reimburse Cidara for the costs incurred in conducting research and development of CD388 under an agreed research plan and budget. Cidara will receive an upfront payment of $27 million and will be eligible to receive up to an additional $753 million, which consists of budgeted R&D funding, as well as development, regulatory and commercial milestones. In addition, Cidara will receive tiered royalties on worldwide sales in the mid-to high-single digits, and will have the option to co-detail CD388 in the United States.

This collaboration represents a tremendous achievement for Cidara and validates the significant potential of our Cloudbreak AVC platform, as well as the incredible innovation and efforts of the Cidara team. Leveraging Janssen's infrastructure and commercial capabilities will be invaluable to the expeditious development of CD388 for influenza on a global scale.

Currently, we believe there is a significant unmet need in the influenza landscape and large market opportunity. We all know influenza as a contagious infection that can cause severe illness, and sometimes it results in death, which is why the CDC recommends that all people over six months of age receive the flu vaccine each year. A 2018 CDC study estimated that about 8% of the U.S. population, or more than 25 million Americans, get sick from the flu in a typical year, even with current vaccination efforts, resulting in a total economic burden of over $11 billion per year.

Current treatment options are often ineffective and viral resistance to existing drugs has been observed. Moreover, current flu vaccines, while critical and still our best defense to date, have two well-known limitations: they don't cover all strains of flu, and they don't cover all people who receive the vaccine. To the first point, vaccines typically cover only three to four of the dozens of flu strains that could become prevalent during a given flu season. The vaccine strains are selected six months before the flu season and, due to antigenic drift, can become less susceptible to the vaccine over time. To my second point, of the 49% of Americans who historically obtain an annual influenza vaccine, about 60% do not adequately respond and remain at risk of getting the flu. In fact, vaccine effectiveness for the 2018-2019 flu season was estimated to be only 29%, with effectiveness rates as low as 12% in people over 65.

Importantly, we designed our influenza AVC, CD388, to address the shortcomings in both the prevention and treatment settings. AVCs are not vaccines, monoclonal antibodies, or traditional therapeutics, but rather they are potent long-acting drugs. As such, they are designed to offer several advantages.

First, in the prevention setting, our preclinical data support the potential for CD388 to provide universal protection from all flu strains tested, both A and B, including both seasonal and pandemic strains. In addition, because AVCs are long-acting drugs that do not require an immune response as a vaccine does, they have demonstrated efficacy in severely immunocompromised mouse infection models, which are intended to represent high-risk populations such as the elderly or immune-compromised. As a result, CD388 has the potential to fulfill our vision that a single dose, given subcutaneously or intramuscularly, could provide universal protection against all strains for all people for an entire flu season.

An additional advantage of AVCs is the time required to achieve protection. Vaccines can have a delay of up to 14 days until they are fully protective, while AVCs are expected to take effect nearly immediately. AVCs also have potential advantages over monoclonal antibodies, which typically have high production costs and limited spectrum that can prohibit their utility for disease prevention in broad populations. Flu AVCs are highly active against A and B, whereas monoclonal antibodies currently in development are only active against A.

Flu AVCs also have advantages in the treatment setting. Importantly, the efficacy window of today's flu treatment options is only about 48 hours, not nearly long enough for most people to benefit from existing therapeutic options. Our preclinical studies demonstrate that flu AVCs may extend that treatment window by up to 24 hours longer, giving AVCs the potential to drastically improve patient responses. Additional preclinical studies demonstrate that flu AVCs have a lower resistance potential compared to approved influenza treatments, as well as near-immediate protective effects.

As a result of these data, we believe AVCs have the potential for fast-acting universal treatment of Influenza A and B, including all major clinically characterized drug-resistant seasonal and pandemic strains. Collectively, flu AVCs such as CD388 have the potential to protect all high-risk groups from all known influenza strains from both a prevention and treatment standpoint, while remaining a cost-effective and scalable option.

In terms of upcoming milestones, we have a very active year planned for the CD388 program. We are currently completing IND-enabling studies for CD388 and expect to file an IND by the end of this year, and to subsequently initiate a Phase 1 study in early 2022. Concurrently, we are scaling manufacturing with a leading contract manufacturer and will direct aspects of CD388 manufacturing.

In summary, we believe the Janssen collaboration we are announcing today validates our vision of the game-changing potential of flu AVCs.

I'd like to turn now to address the opportunities we see in our broader Cloudbreak antiviral platform programs which are not presently partnered. I mentioned earlier that the foundational concept of our Cloudbreak platform is to generate long-acting, antiviral drugs, by linking potent antivirals to a human antibody fragment. With this modular approach we can swap out the influenza antiviral targeting moiety for a different small molecule or peptide antiviral directed against a different pathogen and thereby generate AVCs to target other viral diseases with our immunotherapeutic approach. Our current efforts are focused on RSV, HIV and SARS-CoV-2.

I'll begin with respiratory syncytial virus, or RSV. RSV is the second largest cause of death in children under one year of age worldwide, second only to malaria. There is a significant unmet need for both seasonal and long-term prevention and treatment of RSV for the very young, the elderly and those with weaker immune systems, and currently there is no vaccine for RSV. We believe that there is an unmet need for a therapy can provide broad-spectrum viral coverage with a long duration of action and can also protect high-risk individuals. The encouraging preclinical efficacy of influenza AVCs suggests that the Cloudbreak AVC platform has the potential to address this deficiency in the current landscape for RSV.

Given Janssen's significant research and commercial presence in the field of respiratory viral infections, including RSV, Cidara has granted Janssen an exclusive right of first negotiation, for a limited period of time, to negotiate for and enter into a separate collaboration for the research and development of AVCs addressing RSV.

Moving on to our HIV program, like RSV there is no vaccine for HIV, and long-term prevention and maintenance remain priorities. HIV has a critical unmet need for long-acting, effective drugs and we see the market shifting in that direction. Our RSV, HIV, and SARS-CoV-2 programs will benefit from the learnings from our flu AVC program to accelerate their advancement. We look forward to sharing additional preclinical data on these programs in the near future.

Finally, we are also actively considering other viral diseases to target with our Cloudbreak approach based on technical, clinical and commercial attributes.

Notwithstanding the focus and excitement today regarding our flu AVCs and our collaboration with Janssen, there is more to Cidara than the Cloudbreak antiviral platform. Our most advanced infectious disease program focuses on the attractive systemic antifungal market and we continue to advance our novel long-acting echinocandin, rezafungin, through two Phase 3 clinical trials. The first is the ReSTORE trial, which addresses the treatment of candidemia and invasive candidiasis, and the second is our ReSPECT prophylaxis trial focused on the prevention of invasive fungal disease in patients undergoing allogeneic blood and marrow transplant. Rezafungin, if approved, could transform the standard of care for the treatment and prevention of invasive fungal infections and has the potential to be the first new antifungal in over a decade indicated for both first-line Candida treatment and first-line antifungal prophylaxis. These two Phase 3 trials could position Cidara and rezafungin squarely within both the infectious disease and hematology settings.

The rezafungin program is validated by our partnership with Mundipharma, through which Cidara retains rights for the U.S. and Japan, whereas Mundipharma will commercialize rezafungin in all other regions. As a reminder, we expect topline results from the Phase 3 ReSTORE treatment trial by the end of 2021.

As I begin to wrap up my prepared comments, I'd like to address the positive financial impact of this collaboration on Cidara's future operations. We expect that our strengthened balance sheet, both from the upfront payment and ongoing R&D funding from the Janssen collaboration, as well as the ongoing support

from Mundipharma for our rezafungin Phase 3 clinical trials, provides us with the cash resources necessary to fund our activities past the expected IND filing for CD388 and topline data for the ReSTORE Phase 3 trial. Importantly, both our rezafungin and Cloudbreak platforms are now validated by key strategic partnerships with Mundipharma and Janssen, respectively. On a combined basis, these two collaborations have the potential to provide us up to $1.3 billion in R&D funding and milestone payments, as well as additional royalty payments on commercial sales in the coming years.

In conclusion, the collaboration with Janssen we have announced today is just the beginning of what we believe will be an extraordinarily dynamic time for Cidara. In the past two years, we have entered into two lucrative and validating strategic relationships that financially support our research and development efforts and expand our mission globally. These collaborations are a testament to the credibility of the Cidara team and the compelling potential of, and significant market opportunities for rezafungin and our Cloudbreak AVCs.

With multiple near-term catalysts and attractive long-term potential, Cidara is well-positioned to become an established leader in the antifungal and antiviral therapeutic areas. We are committed to advancing our diverse pipeline of assets to transform the current standard of care for patients and we look forward to providing updates on our progress in the coming months.

With that, I'd like to turn the call back over to the operator so we can address your questions. Operator?

Operator

Thank you. Ladies and gentlemen, at this time we will conduct a question-and-answer session.

Thank you. Our first questions come from the line of Louise Chen with Cantor Fitzgerald. Please proceed with your questions.

Louise Chen

Hi. Congratulations on the deal and thanks for taking my questions here. I have a few.

The first question I have for you is could your AVC be developed to treat both influenza and SARS-CoV2? Then, secondly, when do you expect to have the Phase 2 results and what will that trial design look like? Then lastly, what is the efficacy or anticipated efficacy of your AVC versus the current vaccines? I know you talked about the efficacy rate of those vaccines, but where could your efficacy rate come out? Thank you.

Jeff Stein

Let me address the last question first, Louise.

As we've seen historically with flu vaccines, in the 2018-2019 flu season that was about 29% overall with as low as 12% in the population over 65. We have yet to find—and when I say we I mean we, our partner, NIH who have been testing our flu AVCs including CD388—we have yet to find a flu strain that is not susceptible to CD388 at the expected efficacious exposure. We're very optimistic that this could be in fact a better solution, especially in times of a pandemic.

Can you remind me of the first question, Louise?

Louise Chen

Yes, sure. Does your product or could you make your AVC so that it could protect against both influenza and SARS-CoV2?

Jeff Stein

We have contemplated that. This is a modular approach and because of the way that we can engineer the Fc, we can have a single Fc that can contain two different moieties that target two different viruses. We haven't disclosed any detail on that to date, but it's something that we certainly have contemplated.

Louise Chen

Okay. And what about your Phase 2 result timing? When do you think you'll see that?

Jeff Stein

Well, we expect to file an IND by the end of this year, and we then expect to start Phase 1 shortly thereafter. Historically, the types of single and multiple ascending dose Phase 1s that we contemplate for other indications typically take 9 to 12 months, and after evaluating the data we'll determine the nature of the Phase 2 study and we'll determine the length of time that should take at that point in time, but it will be driven largely off of the results of the Phase 1.

Louise Chen

Thank you.

Operator

Thank you. Our next questions come from the line of Joseph Stringer with Needham & Company. Please proceed with your questions.

Joseph Stringer

Hi everyone. Good morning and congrats on the collaboration and thanks for taking our question.

I was just curious what the—you have 377 and 388 AVC programs. What are sort of the determining factors with 388 as the lead in your discussions with Janssen? Was it sort of the potential for the longer duration or immune engagement, or some of the discussions around that? Thank you.

Jeff Stein

Yes, you've got that right. CD377 and CD388 only differ by the nature of the Fc domain, with CD388 being longer acting. We sought to prioritize CD388 for that attribute. CD377 also falls under this agreement and there is a potential to develop that separately.

Joseph Stringer

Okay, great. Thanks for taking our question.

Jeff Stein

Okay.

Operator

Thank you. Our next questions come from the line of Nathan Weinstein of Aegis Capital. Please proceed with your questions.

Nathan Weinstein

Good morning and congratulations on the announcement today. Very interesting.

I was just hoping to ask a question about the flu market. In light of COVID, the flu season was rather benign but just maybe some thoughts about how it could develop in the future. Do you expect sort of a reversion to the mean in terms of flu incidence?

Jeff Stein

Yes, Nathan. Let me hand that one over to Paul Daruwala, our COO.

Paul Daruwala

Thanks, Nathan. As you know, historically the flu market has been obviously quite interesting, mostly dominated by vaccines So if you've got 49% of the U.S. population that gets a vaccine every year that's almost 150 million people. The CDC still recommends—no change such that everyone over the age of six months gets a vaccine; that's in the U.S. alone so you still have quite a tremendous market.

I think what we've seen this past year, obviously with social distancing and people wearing masks, the change has been quite dramatic. I think what all experts anticipate and we agree is that the flu market will return very similar to the way it has in previous years and some experts may say that it's actually going to be worse when masks lift; much of that because the antigens aren't circulating in the population as they would have otherwise, you may even have a rebound.

Jeff Stein

I would add to that Nathan is that before the coronavirus hit us last year, the major worry was pandemic influenza and so that was one of the reasons why we really prioritized our influenza program. Nobody believes that this will not come back, and to Paul's point, the absence of circulating antigens today actually could lead to a worse flu season coming and that's one of the reasons why we sought to partner with Janssen with their capabilities in conducting very rapid clinical trials in large populations. We couldn't think of a better partner to partner with.

Nathan Weinstein

That's great. Thank you.

I just wonder—and this is conjecture—if vaccination rates won't actually go up more because Americans have had this experience with going in and getting the COVID vaccine, so maybe the vaccination rates for flu in the future seasons will be higher than they were in the past. That obviously helped the market.

Just a question on the AVCs and manufacturing. Obviously it's a really unique and interesting structure. Can you just talk about if you expect manufacturing capability to be in place at the future when you need it?

Jeff Stein

That's certainly the plan. We are currently directing manufacturing and at some point in the development program Janssen will take over the responsibilities for manufacturing. Certainly they have the infrastructure to do that on a very large basis globally.

Nathan Weinstein

Okay, great. Thank you, guys, for taking my questions.

Operator

Thank you.

Our next questions come from the line of Robert Driscoll with Wedbush. Please proceed with your questions.

Robert Driscoll

Thanks. Good morning, guys, and thanks for taking the question.

I think you mentioned it quickly on the call, but can you remind us how the RSV Cloudbreak candidate is designed and how you might expect the development of CD377, CD388 might de-risk that program? Thanks.

Jeff Stein

Yes, Robert. We haven't disclosed the details of the RSV program. Certainly the preclinical data we see today are hot and very compelling, and so this is one of the reasons why we have provided Janssen a right of first negotiation for a limited period of time to advance that program. Because as with influenza, that would be a very broad development program in large populations.

Robert Driscoll

Got it. Thanks very much and congratulations on the collaboration today.

Jeff Stein

Thank you, Robert.

Operator

Thank you. There are no further questions at this time. I would like to hand the call back over to Jeff Stein for any closing comments.

Jeff Stein

Thank you all for joining our call today. We are extremely pleased to share the details of this important transaction, as well as review the significant near-term opportunities that lie ahead for both Cloudbreak and rezafungin.

We appreciate your continued interest in and support of Cidara. Have a good day, everyone.

Operator

Thank you for joining us today. This does conclude this morning's conference call. You may disconnect your lines at this time. Have a great day.