



# WBB Securities, LLC

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## Cidara Therapeutics, Inc. (NasdaqCM: CDTX) Updating Coverage

Maintaining our rating of a Strong Buy

January 24, 2023

And raising our 12-month Price Target to \$7.00

### Rezafungin Approved 14 to 1 by FDA Advisory Committee

Cidara Therapeutics, Incorporated's. (CDTX) drug development candidate, rezafungin, was decidedly approved by the Antimicrobial Drugs Advisory Committee on January 24. Based on the Advisory Committee's deliberation, we believe it is almost certain that rezafungin will receive approval from the FDA. Upon approval, CDTX would receive milestone payments from its collaborators amounting to tens of millions of dollars and it is likely the approval would facilitate a business development agreement in Japan.

Rezafungin is a once-weekly infusion, that will enable outpatient care for those who would otherwise need to stay in the hospital for a week or more to receive daily infusions, those with no other treatment options

and those for whom azole class antifungals are not indicated. The drug is a member of the echinocandin class, which has a known method of action and is in widespread use, plus once-weekly infusion provides a financial benefit for people whose insurance companies don't cover equipment for in-home infusions. We are therefore maintaining our Strong Buy Rating of Cidara and raising our 12-Month Price Target to \$7.00.

Rezafungin's expected FDA approval will provide CDTX with not only significant milestone payment(s) but also provides confirmation of the company's prowess in drug discovery and development. CDTX's Cloudbreak® platform is a novel approach focused on a new generation of therapeutics to treat solid tumor cancers. The treatments link an anti-cancer drug with a fragment from the Fc region of an antibody. The resulting Drug Fc Conjugates (DFCs) interact with Fc cell surface receptors to mediate adenosine signaling, a portion of the innate immune system that suppresses the tumor-protective immune response. CDTX's first oncology drug-Fc conjugate is CBO-212, targeting CD73, which contributes to immune evasion in solid cancers by flooding the microenvironment surrounding tumors with adenosine.

DFCs have the potential to generate robust anti-tumor activity at 2/3 the dose and half the frequency of the standard of care. DFCs can deliver either biologic or small molecule agents individually or a combination of both biologic and small molecule payloads on the same Fc fragment. This dual delivery capability is important because biologic agents must penetrate the cell wall to deliver toxic agents inside a cell, and small molecules can block receptors outside the cell to inhibit or disrupt surface cellular targets that are important for disease progression.

CDTX is advancing DFC programs to deliver immuno-oncology therapeutics to multiple cancers. The same DFC technology is being used to develop antiviral preventive and

<b>Current Price</b>	<b>\$0.97</b>
<b>12 Month Target Price</b>	<b>\$7.00</b>
12 Month Trading Range	\$0.40-\$1.60
Market Capitalization (Mil)	\$69,044
Shares Outstanding (Mil)	71.18
Avg. Daily Volume	613,911
L. T. Debt (Mil)	N/A
Dividend/Yield	N/A
Book Value P/S	\$0.13
NASDAQ Composite	11,334.27
S&P 500	4,016.95
Historical Performance – Page 9 Price and Volume Chart – Page 10	

therapeutic treatments for types A and B influenza, and other life-threatening viruses, such as SARS-CoV-2.

## Valuation

### Rating Legend:

**Strong Buy** – Should be aggressively purchased.

**Buy** – Should be purchased on market weakness.

**Hold** – Fairly valued.

**Sell** – Stock should be sold on market strength.

**Sell Short** – Should be aggressively sold.

**Speculative Buy** – For aggressive accounts only.

**Core Holding** — Essential holding of a long-term account.

Given today's FDA 14 to 1 vote for approval of rezafungin, we believe that CDTX has proven itself to be a franchise with drug discovery and development prowess. And even in these unpredictable healthcare capital markets with risk avoidance as a chief part in any valuation model, this expertise must be recognized.

As such, our investment thesis remains unchanged and we still use a sum-of-the-parts calculation to arrive at CDTX's value by now assigning a cash value of \$1 per share (our modelling includes rezafungin milestone payments), \$4 per share for the Cloudbreak platform assets \$1 per share of value for the other rezafungin opportunities, and \$1 per share for the balance of CDTX's assets. Using a 71.18 MM undiluted share count, we arrive at our 12-month valuation of \$7.00.

## Cloudbreak Platform

Cidara's Cloudbreak antiviral platform couples a tumor inhibiting or cytotoxic antiviral with a human antibody fragment (Fc) that targets the cell surface of solid tumors and virus species such as influenza and SARS. DFCs have the potential to treat all strains of influenza and SARS.

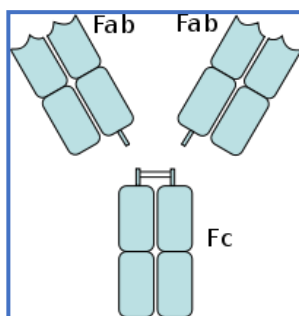
Flu DFCs have the potential to offer near-immediate protection, against all strains for all people, including those with compromised immune systems. The lead CDTX anti-viral product is the Anti-Viral Conjugate (AVC) CD388 for prevention and treatment of influenza. CD388 was created using the proprietary Cloudbreak platform. In addition to influenza, CDTX envisions the Cloudbreak platform capable of creating AVCs to treat RSV, HIV, SARS-CoV-2 infections and others.

Preclinical efforts are ongoing to prepare for an NDA for a cytotoxic DFC. Cytotoxic DFCs have the potential to become novel combination treatments for cancer

Preclinical studies in models of colorectal cancer demonstrate CD73 DFCs have robust anti-tumor activity despite being dosed at half the frequency and at 2/3 the dose of the standard of care. Preclinical studies on CD73/A2AR dual targeting DFCs are ongoing.

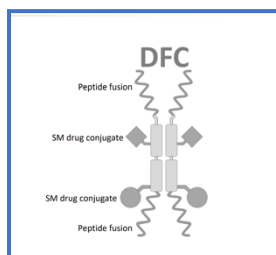
## Drug Fc Conjugates (DFCs)

Drug Fc Conjugates are created by attaching a payload to the fragment crystallizable (Fc) region of an antibody.



Source: Wikimedia Commons

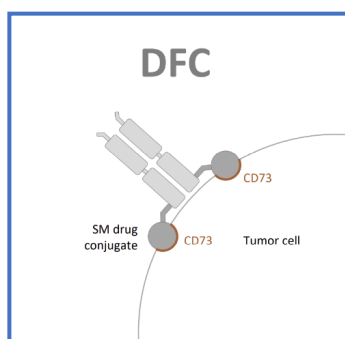
Shown here is a DFC with a cytotoxin payload that includes both a peptide and small molecule drug attached.



Source: CDTX Presentation

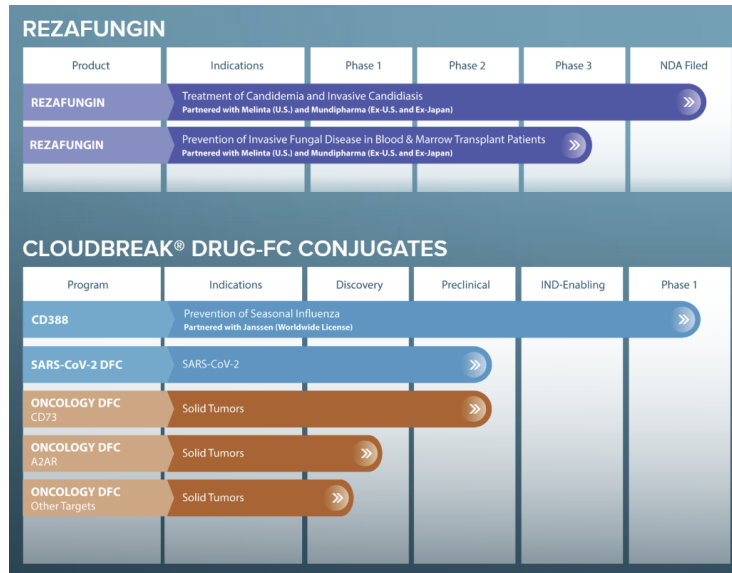
CDTX's most advanced oncology program is the creation of DFCs that inhibit CD73, a receptor that generates adenosine, which shields a tumor from being cleared by the host immune system.

CDTX also is developing DFCs to protect against all variants of both the SARS-CoV-2 and seasonal influenza viruses.



Source: CDTX Web Site

## Cidara Development Pipeline



Source: Cidara Therapeutics, Inc. Web Site 01/12/23

## Clinical Stage Candidates

**Rezafungin** is a novel broad-spectrum anti-fungal, echinocandin that is active against both wild-type and a subset of azole and echinocandin-resistant strains of *Candida*, *Aspergillus* and *Pneumocystis*. Echinocandins are considered the safest antifungal drugs available and are suggested by the Infectious Disease Society of America (IDSA) as first-line treatment for fungal infections. Rezafungin is intended to be administered once-weekly to treat candidemia and invasive candidiasis, and to be used as a prophylaxis for invasive fungal infections in patients undergoing allogeneic blood and marrow transplant.

*Candida auris* is the number two urgent threat identified by the CDC in its report – Antibiotic Resistance Threats In the United States, published November 14, 2019. The following is taken from that report. “*C. auris* has quickly become a cause of severe infections around the world. Therapeutic options for fungal infections are limited even before considering antifungal resistance. *C. auris* is often multidrug-resistant, with some strains resistant to all three available classes of antifungals. CDC encourages all U.S. laboratory staff who identify *C. auris* to notify their state or local public health authorities and CDC at [candidaauris@cdc.gov](mailto:candidaauris@cdc.gov).”

The CDC reports COVID-19 likely increases the risk for fungal infections because of its effect on the immune system and because treatments for COVID-19, like steroids and other drugs, can weaken the body’s defenses against fungi. The most commonly reported fungal infections in patients with COVID-19 include aspergillosis, invasive candidiasis, and mucormycosis.

The FDA has designated rezafungin as a Qualified Infectious Disease Product (QIDP), Fast Track Product and orphan drug for the treatment of candidemia and invasive candidiasis. These designations will provide rezafungin with 12 years of potential marketing exclusivity in the U.S.

at the time of FDA approval. QIDP designation is reserved for antibacterial and antifungal drug candidates intended to treat serious or life-threatening infections.

Rezafungin announced completion of the Phase 3 trial (ReSTORE) trial for treatment of fungal infections caused by *Candida* spp, including candidemia and candidiasis on August 17, 2021.

The ongoing Phase 3 trial (ReSPECT) trial is examining rezafungin for prevention of fungal infections caused by *Candida*, *Aspergillus* and *Pneumocystis* in patients undergoing blood and marrow transplants.

On September 3, 2019 Mundipharma Medical acquired exclusive rights to develop and commercialize rezafungin in all markets outside of the U.S. and Japan and on July 27, 2022 CDTX entered into a commercial partnership with Melinta Therapeutics to commercialize rezafungin in the U.S.

CDTX received a \$30 million upfront payment from Melinta and is eligible to receive \$60 million in regulatory milestone payments and up to \$370 million in commercial milestone payments, representing a total potential transaction value of \$460 million, plus royalties on tiers of annual net sales of rezafungin in the U.S.

On July 27, 2022 CDTX submitted an NDA for rezafungin as a treatment for candidemia and invasive candidiasis. On September 20, 2022, CDTX announced that the FDA accepted the NDA and assigned a Prescription Drug User Fee Act (PDUFA) target action date of March 22, 2023.

On October 4, 2022, CDTX announced receipt of an \$11 million milestone payment from Mundipharma. CDTX remains eligible to receive additional non-dilutive capital of up to approximately \$108 million in development and regulatory milestones from existing partnerships based on successful completion of activities planned for the next two years.

**CD388** is a long-acting antiviral immunotherapy designed to deliver universal protection against infection for an entire influenza season. CD388 has the potential to protect individuals from all influenza strains, including seasonal and pandemic influenza A, influenza B and major clinically characterized drug resistant influenza strains.

CDTX holds Patent No. 11,510,992, for CD388, titled Compositions and Methods for the Treatment of Viral Infections. The patent is projected to expire in 2039 plus any available patent term extension.

CDTX has an exclusive worldwide license and collaboration agreement with Janssen Pharmaceuticals, Inc., one of the Janssen Pharmaceutical Companies of Johnson & Johnson (JNJ), to develop and commercialize Cloudbreak antiviral conjugates (AVCs) for the prevention and treatment of seasonal and pandemic influenza.

CDTX is responsible for the development and manufacturing of CD388 through Phase 2 clinical trials. Janssen is funding all research, development, manufacturing and commercialization of

CD388. Janssen also will be responsible for late-stage development, manufacturing, registration and global commercialization. CDTX has the option to co-detail CD388 in the U.S.

In addition to the JNJ \$27 million upfront payment, CDTX is eligible to receive up to an \$753 million in R&D funding and in development, regulatory and commercial milestones, plus tiered royalties on worldwide sales.

CD388 is now undergoing a Phase 2a trial with up to 168 healthy adults to evaluate the pre-exposure prophylactic activity of CD388 against influenza virus. The trial (NCT05523089), dosed its first volunteer on September 10<sup>th</sup>, 2022 and results are expected in 1H-2023. It is a single-center, randomized, double-blind, placebo-controlled, proof-of-concept study to assess the prophylactic antiviral activity, safety, tolerability and pharmacokinetics of CD388 against influenza. Volunteers will receive a single administration of one of several dose levels of CD388 or placebo prior to influenza viral challenge.

## Management

**Jeffrey Stein, Ph.D., President and Chief Executive Officer** since January 2014. Prior to joining Cidara, Dr. Stein was President and CEO of Trius Therapeutics, Inc. from its founding in 2007 until its acquisition by Cubist Pharmaceuticals, Inc. in 2013. Previously, Dr. Stein was a venture partner and Kauffman Fellow at Sofinnova Ventures, co-founder and Chief Scientific Officer at Quorex Pharmaceutical, Inc. and a Principal Scientist with Diversa Corporation and the Agouron Institute. Dr. Stein currently serves as a Director at Paratek Pharmaceuticals and Ideaya Biosciences. Dr. Stein is also the founding Chairman and President of the Antibiotics Working Group. Dr. Stein holds a B.S. in marine biology, an M.S. in biology from California State University – Long Beach and a Ph.D. in marine biology from the University of California, San Diego. Dr. Stein conducted his postdoctoral research in bacterial genetics as an Alexander Hollaender Distinguished Postdoctoral Fellow at the California Institute of Technology.

**Allison Lewis, SPHR, CCP, Vice President, Human Resources** since February 2015. Prior to joining Cidara, Ms. Lewis was a member of the Human Resources teams at Cadence Pharmaceuticals and, subsequently, Mallinckrodt Pharmaceuticals after its acquisition of Cadence in 2014. Ms. Lewis also held HR management roles of increasing responsibility at PPD, Applied Technology and Management and IGY. Ms. Lewis received her bachelor's degree in business from University of Florida and holds designations as a Senior Professional in Human Resources (SPHR), SHRM Senior Certified Professional (SHRM-SCP), and a Certified Compensation Professional (CCP). She leverages her expertise in service on the board of LifeHR, a San Diego Life Sciences HR association.

**Laura Navalta, Senior Vice President of Clinical Operations** since 2017. Prior to joining Cidara, Ms. Navalta served as Chief Operating Officer at C3 Jian Therapeutics and Novalar Pharmaceuticals, and Executive Director of Clinical Operations at Vical, Inc. Ms. Navalta holds a B.A. in Development Psychology from the University of Southern California.

**Taylor Sandison, M.D., M.P.H., Chief Medical Officer** since April 2017 and acting chief medical officer since September 2016. He joined Cidara in October 2015 as the VP of Clinical

Development. Prior to joining Cidara, he served as senior medical director at Merck and prior to that, held the same position at Cubist Pharmaceuticals, Inc. Dr. Sandison also has held positions at Trius Therapeutics and Novartis Diagnostics, and served as a member of the faculty in the Department of Medicine at both Stanford University and the University of Washington. He received B.S. and B.A. degrees from Dartmouth College and an M.P.H. degree from the University of Washington. Dr. Sandison currently holds board certifications in Infectious Diseases and Internal Medicine.

**Preetam Shah, PhD, MBA, Chief Financial Officer and Chief Business Officer** since September 1, 2021. Dr. Shah previously served as Executive Vice President, Chief Financial Officer and Treasurer at Brainstorm Cell Therapeutics, Inc., six years as an investment banker at Barclays Capital PLC. and Canaccord Genuity Inc., founder of Saisarva LLC, a healthcare consulting firm, Vice President, U.S. Operations and Investments at Reliance Capital USA Ventures LLC. Dr. Shah completed his post-doctoral fellowship in Infectious Diseases from Stanford University School of Medicine. He holds a Ph.D. in Microbiology from the University of Mississippi Medical Center, an M.B.A. in Finance from the Wharton School, University of Pennsylvania, and a B.A. in Mathematics and in Biology from McDaniel College.

**Les Tari, Ph.D., Chief Scientific Officer** since 2014. Prior experience includes various positions at Trius Therapeutics until its acquisition by Cubist Pharmaceuticals, co-founder and Director of Structural Biology at ActiveSight, Inc. and an academic position as an Alberta Heritage Foundation Scholar for Medical Research at the University of Calgary. Dr. Tari holds a B.Sc. in Chemistry and a Ph.D. in Chemistry and Structural Biology from the University of Manitoba.

**Carol Waldo, Senior Vice President Regulatory Affairs and Quality Assurance** joined Cidara on May 13, 2021. Before joining Cidara, Ms. Waldo was the head of regulatory affairs at Spero Therapeutics, Vice President of Regulatory Affairs at Cubist Pharmaceuticals, Global Regulatory Leader at Amgen for ENBREL, PROLIA, and other programs. Ms. Waldo holds a Bachelor of Arts from North Central College and Regulatory Affairs Certification (US, EU, CAN) from the Regulatory Affairs Professional Society.

**Shane Ward, Chief Operating Officer and Chief Legal Officer** is a licensed attorney. Prior to joining Cidara, Mr. Ward was Chief Legal and Strategy Officer for Bellicum Pharmaceuticals and served commercial and development-stage biotechnology companies, including Gilead Sciences, Human Genome Sciences, and Versartis. Mr. Ward holds a J.D. from the Georgetown University Law Center and a B.A. from the University of Virginia.

## Risks

***Disclosure Controls and Procedures:*** The 3Q-2022 10Q reported that disclosure controls and procedures were not effective at the reasonable assurance level as of September 30, 2022 due to a material weakness in internal control over financial reporting. The company wrote that management is in the process of implementing a remediation plan, which includes adding additional layers of review by members of the management team regarding the evaluation of

applicable accounting standards and completeness and accuracy of valuation assumptions related to non-routine transactions that include collaboration revenue.

**Clinical Risk:** A delay, termination or suspension of clinical trials for rezafungin, CD388 or other product candidates, or failure to demonstrate safety and efficacy to the satisfaction of regulatory authorities, could cause additional costs or delays in completing, or prevent completion, the development and commercialization of product candidates.\*

**Intellectual Property Risk:** CDTX may be challenged by other competitors regarding the validity of patents and IP. CDTX has made an effort to create strong IP protection around the company's therapies. As of February 27, 2018, the patent portfolio included 12 families of patent applications related to various aspects of rezafungin, and nine families of patent applications related to the Cloudbreak platform. CDTX is not currently involved in litigation, but may be involved in the future, to protect or enforce patents or the patents of licensors, which could be expensive, time consuming and unsuccessful.

**Competitive Risk:** Although CDTX products and its proprietary platform are highly differentiated, the development landscape continues to be an area where new candidates are introduced frequently. We cannot be certain about the market uptake of eventual therapies derived from CDTX's technologies, usage in the medical community and how size the market will ultimately be. Larger Large-Cap companies would have more resources to bring their candidates to market, along with revenue from previous successful market launches.

**Financing Risk** CDTX reports it needs substantial additional funding to complete the development of rezafungin and to advance CD388. Based on the company's current business plan, existing cash and cash equivalents will not be sufficient to fund obligations for the next twelve months. Completing Phase 3 trials of rezafungin and continuing advancement of CD388 depends on the ability to obtain additional funding.



## Historical and Future EPS Performance

<b>EPS</b>	<b>2021</b>	<b>2022</b>	<b>2023</b>
Q1	(0.39)A	(0.27)A	(0.25)E
Q2	(0.18)A	(0.19)A	(0.00)E
Q3	(0.37)A	(0.17)A	(0.25)E
Q4	0.14 A	(0.23)E	(0.25)E
Year	(0.81)A	(0.86)E	(0.75)E
P/E			
EPS Growth	NM	NM	NM
FY Rev. (Mil)	49.572A	54.00E	30.00E
<b>FY:DEC</b>			
<small>*Collaboration Revenue</small>			

Other companies mentioned in this report:

Johnson & Johnson (JNJ)  
Mundipharma (private)  
Melinta Therapeutics (private)

## Price and Volume

Initiated Coverage of Cidara on 04/23/15



- |          |  |
|----------|--|
| <b>1</b> | Updated Coverage of Cidara on 12/04/2019 at \$2.37 with a Buy Rating and a 12-Month Price Target of \$6.25.        |
| <b>2</b> | Updated Coverage of Cidara on 09/22/2021 at \$2.14 with a Strong Buy Rating and a 12-Month Price Target of \$6.25. |
| <b>3</b> | Updated Coverage of Cidara with a Morning Note on 12/14/21 at \$1.38 and A 12-Month Price Target of \$6.25.        |

Distribution of Ratings and Disclosure of Banking Relationships: The following table shows WBB's ratings distribution expressed as a percentage of all securities rated as of the end of the most recent calendar quarter, as well as the percentage of subject companies within each rating category for whom WBB has provided investment banking services within the previous 12 months.

	Percentage of Covered Securities	Percentage of Banking Clients
Buy	84%	6.25%
Hold	11%	%
Sell	05%	%

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