Cidara Provides Corporate Update and Reports First Quarter 2021 Financial Results

May 13, 2021

SAN DIEGO, May 13, 2021 (GLOBE NEWSWIRE) -- Cidara Therapeutics, Inc. (Nasdaq: CDTX), a biotechnology company developing long-acting therapeutics designed to transform the standard of care for patients facing serious fungal or viral infections, today reported financial results for the three months ended March 31, 2021 and provided an update on its corporate activities and product pipeline.

“We were pleased to recently announce our worldwide license and collaboration agreement with Janssen for the development and commercialization of our Cloudbreak® influenza AVCs,” said Jeffrey Stein, Ph.D., president and chief executive officer of Cidara. “The Janssen collaboration and our previously announced collaboration with Mundipharma for the development and commercialization of rezafungin, our novel, once-weekly echinocandin, validate our antiviral and antifungal product pipelines, respectively, and demonstrate the significance of the unmet need in these areas. Importantly, we continue to anticipate filing an IND for our lead influenza candidate, CD388, as well as announcing top-line data from the ongoing Phase 3 ReSTORE trial for rezafungin by the end of 2021.”

Recent Corporate Highlights

- **Announced agreement with Janssen Pharmaceuticals for the development and commercialization of our influenza Antiviral Conjugates (AVCs), including CD388:** In March, Cidara entered into a worldwide license and collaboration agreement with Janssen Pharmaceuticals, one of the Janssen Pharmaceutical Companies of Johnson & Johnson, to develop and commercialize Cidara’s Cloudbreak AVCs for the prevention and treatment of seasonal and pandemic influenza. Under the terms of the collaboration, Cidara will receive an upfront payment of $27 million and will be eligible for up to $753 million in budgeted research and development funding and milestone payments, plus tiered royalties on worldwide sales in the mid to high single digits. Janssen will fund all future research, development, manufacturing and commercialization for CD388. The agreement became effective on May 12, 2021 following the expiration of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act entitling us to receive the $27 million upfront payment within 10 business days of the effective date.

- **Granted Orphan Drug Designation (ODD) for rezafungin:** In January, the European Commission adopted the European Medicines Agency’s Committee for Orphan Medicinal Products recommendation to grant ODD to rezafungin for the treatment of invasive candidiasis.

- **Announced new data at ICHS Symposium:** In February, Cidara announced data from three posters highlighting new clinical and preclinical data on rezafungin at the 21st International Immunocompromised Host Society (ICHS) Symposium on Infections in the Immunocompromised Host. In an analysis of outcomes from the completed Phase 2 STRIVE trial of rezafungin for the treatment of candidemia and/or invasive candidiasis the overall response rate, investigator-assessed clinical cure and mycological response at Day 14 was 75% (9/12) in high-risk immunocompromised patients treated with rezafungin compared to 66.7% (6/9) in those treated with standard of care (caspofungin). Further evaluation of patients from the STRIVE trial based on renal function demonstrated that the safety and efficacy of rezafungin were not adversely affected by renal impairment, a common comorbidity in critically ill patients with invasive fungal infections.

- **Participated in two investor conferences:** Cidara recently participated in the H.C. Wainwright Global Life Sciences Conference and 20th Annual Needham Virtual Healthcare Conference.

- **Strengthened management team through key hire:** In May 2021, Cidara appointed biotech industry veteran Carol Waldo as Senior Vice President of Regulatory Affairs and Quality Assurance.

First Quarter 2021 Financial Results

- Revenue totaled $2.4 million for the three months ended March 31, 2021, compared with $2.5 million for the same period of 2020.

- Cash, cash equivalents and restricted cash totaled $48.8 million as of March 31, 2021, compared with $42.9 million as of December 31, 2020.

- As of March 31, 2021, Cidara had 48,288,670 shares of common stock outstanding, and 1,044,278 shares of Series X convertible preferred stock outstanding, which are convertible into 10,442,780 shares of common stock.

- Research and development expenses were $15.8 million for the three months ended March 31, 2021, compared to $13.0

million for the same period in 2020. The increase was primarily attributable to higher clinical expenses associated with the rezafungin clinical trials, increased expense associated with our Cloudbreak antiviral platform, and higher personnel costs.

- General and administrative expenses were $4.8 million for the three months ended March 31, 2021, compared to $4.1 million for the same period in 2020.

- Net loss for the three months ended March 31, 2021 was $18.3 million, compared to a net loss of $14.5 million for the first quarter of 2020.

About Cidara Therapeutics
Cidara is developing long-acting therapeutics designed to transform the standard of care for patients facing serious fungal or viral infections. The Company's portfolio is comprised of its lead antifungal candidate, rezafungin, in addition to AVCs for the prevention and treatment of influenza and other viral diseases from Cidara's proprietary Cloudbreak® antiviral platform. Cidara is headquartered in San Diego, California. For more information, please visit www.cidara.com.

Forward-Looking Statements
This release contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and such forward-looking statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. "Forward-looking statements" describe future expectations, plans, results, or strategies and are generally preceded by words such as "anticipates," "expect," "may," "plan" or "will". Forward-looking statements in this release include, but are not limited to, statements related to our plans to file an IND for CD388 and receive top-line data for the Phase 3 ReSTORE trial by the end of 2021, and the receipt of payments under the Janssen agreement. Such statements are subject to a multitude of risks and uncertainties that could cause future circumstances, events, or results to differ materially from those projected in the forward-looking statements, such as unanticipated delays in or negative results from Cidara's pre-clinical or clinical trials, impacts of the COVID-19 pandemic or other obstacles to the development of CD388. These and other risks are identified under the caption "Risk Factors" in Cidara's most recent Quarterly Report on Form 10-Q and other filings subsequently made with the Securities and Exchange Commission. All forward-looking statements contained in this press release speak only as of the date on which they were made and are based on management's assumptions and estimates as of such date. Cidara does not undertake any obligation to publicly update any forward-looking statements, whether as a result of the receipt of new information, the occurrence of future events or otherwise.

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CIDARA THERAPEUTICS, INC.

Condensed Consolidated Statements of Operations (unaudited)

	Three Months Ended March 31,	
(In thousands, except share and per share data)	**2021**	**2020**
Revenues:		
Collaboration revenue	$ 2,408	$ 2,530
Total revenues	2,408	2,530
Operating expenses:		
Research and development	15,849	12,996
General and administrative	4,781	4,095
Total operating expenses	20,630	17,091
Loss from operations	(18,222)	(14,561)
Other income (expense):		
Interest income (expense), net	(70)	22
Total other income (expense), net	(70)	22
Net loss and comprehensive loss	(18,292)	(14,539)
Recognition of beneficial conversion feature	—	(2,762)
Net loss attributable to common shareholders	$ (18,292)	$ (17,301)
Basic and diluted net loss per common share	$ (0.39)	$ (0.46)
Shares used to compute basic and diluted net loss per common share	46,967,213	37,856,338

Condensed Consolidated Balance Sheet Data

(In thousands)	**March 31, 2021** (unaudited)	**December 31, 2020**
Cash, cash equivalents, and restricted cash	$ 48,789	$ 42,949
Total assets	54,210	60,424
Term loan	5,916	7,023
Total liabilities	52,318	49,709
Total stockholders' equity	1,892	10,715