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ContraFect Reports Second Quarter 2021 Financial Results and Provides Business Update

Multiple peer-reviewed journal publications and presentations at scientific forums drive value and recognition across the Company's DLA portfolio

Continued patient enrollment in ongoing Phase 3 DISRUPT study of exebacase

YONKERS, N.Y., Aug. 13, 2021 (GLOBE NEWSWIRE) -- [ContraFect Corporation \(Nasdaq: CFRX\)](#), a late clinical-stage biotechnology company focused on the discovery and development of direct lytic agents (DLAs), including lysins and amurin peptides, as new medical modalities for the treatment of life-threatening, antibiotic-resistant infections, today announced financial results and business updates for the second quarter ended June 30, 2021.

“ContraFect has positively executed on every program in our portfolio. We published several significant manuscripts and presented data that highlights the potential of our DLAs to meaningfully improve patient outcomes of many different life-threatening bacterial infections. Most importantly, we have continued to enroll patients in our Phase 3 DISRUPT superiority study of exebacase in patients with *Staph aureus* bloodstream infections, throughout the entire ongoing COVID-19 pandemic. Since the beginning of the year, we remained on track with our expected enrollment timelines. The recent increase in the number of COVID-19 infections and hospitalizations is continuing to impact the healthcare system, including the conduct of clinical trials in the US and other parts of the world. As such, we are now seeing effects of the pandemic on our trial, and our most recent monthly patient enrollment rate has slowed. As the pandemic evolves, we will continue to evaluate the impact of variable monthly patient enrollment rates on conducting the interim futility analysis by the end of the year,” said Roger J. Pomerantz, M.D., President, Chief Executive Officer, and Chairman of ContraFect.

Recent Corporate Highlights

- In July, ContraFect announced multiple presentations, including two oral presentations, highlighting data from its portfolio of DLAs from the 31st European Congress of Clinical Microbiology & Infectious Diseases (ECCMID). New *in vitro* data supports the potential for the Company's lead lysin, exebacase, to treat *Staph aureus* bone and joint

infections. New data also provide additional evidence supporting that CF-370 could be a potential new asset in the armamentarium against multidrug-resistant Gram-negative pathogens. The presentations are available on the [ContraFect website](#).

- In July, the Company announced the publication of two manuscripts that demonstrate the potent *in vivo* activity of CF-296, a novel engineered lysin agent with potent bactericidal and anti-biofilm activity against *Staph aureus*. The manuscript published in [Antimicrobial Agents and Chemotherapy](#), a leading peer-reviewed journal dedicated to the study of infectious diseases, presented data from a study of CF-296 in a preclinical rodent model of acute methicillin-resistant *Staph aureus* (MRSA) osteomyelitis. The analysis of bone samples demonstrated that CF-296 has potent anti-staphylococcal activity and, when used with daptomycin, is active in acute MRSA osteomyelitis. In a second manuscript published in the peer-reviewed [Journal of Antimicrobial Chemotherapy](#), CF-296 demonstrated efficacy, both as a mono therapy and as an addition to standard-of-care antibiotics, in a preclinical murine model of infection. The addition of CF-296 to both daptomycin or vancomycin resulted in significantly enhanced antibacterial activity in the model, relative to the activity of these anti-staphylococcal antibiotics alone.
- In June, ContraFect announced that Gary Woodnutt, Ph.D. was appointed as Senior Vice President of Translational Sciences and Preclinical Development. Dr. Woodnutt will oversee the scientific strategy for the Company's early-stage assets and the performance of the extensive translational programs required to proceed into clinical trials. He will have a pivotal role in the scientific strategy for the early development of the Company's portfolio of products and the preclinical aspects of Investigational New Drug (IND) applications, as well as in the potential BLA for exebacase. Dr. Woodnutt has over 30 years of experience leading the discovery and early development of innovative therapies ranging from antibiotics to novel protein-based therapeutics.
- In June, the Company announced multiple presentations, including two oral presentations, of data from its portfolio of direct lytic agents at the 2021 World Microbe Forum. Research findings demonstrate the breadth of antimicrobial activity of CF-370 and other ContraFect development candidates against a wide range of Gram-negative pathogens known to cause life-threatening bacterial infections. ContraFect delivered two oral presentations and presented three posters, available on the [World Microbe Forum](#) website to registered attendees. The presentation posters are available on the ContraFect website.
- In May, ContraFect announced multiple publications on exebacase, including the first manuscript on local administration of lysin for the potential treatment of prosthetic joint infections. This publication in [Frontiers in Medicine](#) highlighted the administration of exebacase, arthroscopically, in the setting of debridement (arthroscopic removal of the infected tissue) in patients with relapsing multidrug resistant (MDR) *Staphylococci epidermidis* (*S. epidermidis*) prosthetic knee infection. The company also announced two additional publications of a novel method for the clinical determination of the susceptibility of *Staphylococci* to exebacase for use in the clinical setting.
- In May, the Company announced that the United States Patent and Trademark Office issued U.S. Patent No. 10,988,520 (the '520 patent) on April 27, 2021 for CF-370, the next potential therapeutic product candidate to advance towards an IND submission.

The '520 patent, which is owned by ContraFect, expires in March of 2039, and is the latest U.S. patent to issue from the Company's DLA patent portfolio.

- In April, ContraFect participated in the Cystic Fibrosis (CF) Target Product Profile (TPP) Virtual Symposium. The symposium was established by the CF Syndicate in Antimicrobial Resistance (AMR) and is supported by the Cystic Fibrosis Trust and The Medicines Discovery Catapult, both United Kingdom based organizations fostering cutting-edge therapeutic research.

Second Quarter 2021 Financial Results

- Research and development (R&D) expenses were \$7.8 million for the second quarter of 2021 compared to \$5.5 million in the comparable period in 2020. This increase was primarily attributable to an increase in expenditures for non-clinical studies of exebacase, CF-370, CF-296 and the amurin peptides, as all programs continued to progress forward, an increase in CRO and investigator site expenses related to the execution of the Phase 3 DISRUPT study, and an increase in clinical development and manufacturing headcount and related personnel costs to support the ongoing development of exebacase.
- General and administrative (G&A) expenses were \$2.9 million for the second quarter of 2021 compared to \$2.6 million in the comparable period in 2020. This increase was primarily attributable to increases in administrative personnel costs and professional fees.
- Net loss was \$5.4 million, or a loss of \$0.14 per share, for the second quarter of 2021 compared to net loss of \$17.6 million, or a loss of \$0.88 per share, for the comparable period in 2020. The net loss per share in the current period includes a \$5.3 million, or \$0.13 per share, non-cash gain from the change in the fair value of the Company's warrant liabilities. In the prior year period, the net loss per share included a \$7.3 million, or \$0.37 per share, non-cash charge from the change in the fair value of the Company's warrant liabilities and a \$2.2 million, or \$0.11 per share, non-cash charge for offering expenses allocated to the warrants issued in the Company's May 27, 2020 offering of securities.
- As of June 30, 2021, ContraFect had cash, cash equivalents and marketable securities of \$74.7 million.

About DISRUPT:

The Phase 3 DISRUPT study of exebacase is a randomized, double-blind, placebo-controlled clinical study conducted in the U.S. to assess the efficacy and safety of exebacase in approximately 350 patients with complicated *Staph aureus* bacteremia, including right-sided endocarditis. Patients enrolled in the Phase 3 study are randomized 2:1 to receive either exebacase or placebo, with all patients receiving standard of care (SOC) antibiotics. The primary efficacy endpoint of the study is clinical response at Day 14 in patients with MRSA bacteremia, including right-sided endocarditis. Key secondary endpoints include clinical response at day 14 in the All *Staph aureus* patients (MRSA and methicillin-sensitive *Staph aureus* (MSSA)), 30-day all-cause mortality in MRSA patients, and clinical response at later timepoints. An independent Data Safety Monitoring Board (DSMB) will

conduct the interim futility analysis after 60% of the study population completes the Day 14 primary endpoint study visit.

About Exebacase (CF-301):

Exebacase is a recombinantly-produced lysin (cell wall hydrolase enzyme) with potent bactericidal activity against *Staph aureus*, a major cause of bloodstream infections (BSIs) also known as bacteremia. In the Company's Phase 2 study of exebacase, a pre-specified analysis of MRSA-infected patients showed that the clinical responder rate at Day 14 in patients treated with exebacase was nearly 43-percentage points higher than in patients treated with SOC antibiotics alone (74.1% for patients treated with exebacase compared to 31.3% for patients treated with SOC antibiotics alone (p=0.010)). In addition to the higher rate of clinical response, MRSA-infected patients treated with exebacase showed a 21-percentage point reduction in 30-day all-cause mortality (p=0.056), a four-day lower median length of hospital stay and meaningful reductions in hospital readmission rates. Exebacase is currently being studied in the Phase 3 DISRUPT superiority design study of exebacase in patients with *Staph aureus* bacteremia, including right-sided endocarditis.

Exebacase has the potential to be a first-in-class treatment for *Staph aureus* bacteremia. Exebacase was licensed from The Rockefeller University and is being developed at ContraFect.

About CF-370:

CF-370 is an investigational first-in-class therapeutic candidate targeting *P. aeruginosa*, a Gram-negative pathogen. CF-370 has been engineered to bypass the outer membrane of the bacteria and to enable potent activity in human serum. The Company believes this is a significant milestone for direct lytic agents as native lysins are typically unable to penetrate the outer membrane of Gram-negative bacteria. However, based on the proprietary methods the Company has identified and utilizes to engineer lysins, CF-370 has exhibited the microbiologic attributes of the lysin class, including rapid and potent bactericidal activity, synergy with a broad range of standard of care antibiotics and the eradication of biofilms in preclinical studies. The promising data from animal models support the potential therapeutic utility of CF-370 for the treatment of serious infections caused by *P. aeruginosa*.

About ContraFect:

ContraFect is a biotechnology company focused on the discovery and development of DLAs, including lysins and amurin peptides, as new medical modalities for the treatment of life-threatening, antibiotic-resistant infections. An estimated 700,000 deaths worldwide each year are attributed to antimicrobial-resistant infections. We intend to address life threatening infections using our therapeutic product candidates from our platform of DLAs, which include lysins and amurin peptides. Lysins are a new class of DLAs which are recombinantly produced antimicrobial proteins with a novel mechanism of action associated with the rapid killing of target bacteria, eradication of biofilms and synergy with conventional antibiotics. Amurin peptides are a novel class of DLAs which exhibit broad-spectrum activity against a wide range of antibiotic-resistant Gram-negative pathogens, including *P. aeruginosa*, *Acinetobacter baumannii*, and *Enterobacter* species. We believe that the properties of our lysins and amurin peptides will make them suitable for targeting antibiotic-resistant organisms, such as MRSA and *P. aeruginosa*, which can cause serious infections such as

bacteremia, pneumonia and osteomyelitis. We have completed a Phase 2 clinical trial for the treatment of *Staph aureus* bacteremia, including endocarditis, with our lead lysin candidate, exebacase, which is the first lysin to enter clinical studies in the U.S. Exebacase, currently being studied in a pivotal Phase 3 clinical study, was granted Breakthrough Therapy designation by the FDA for the treatment of MRSA bloodstream infections, including right-sided endocarditis, when used in addition to SOC anti-staphylococcal antibiotics.

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Activities related to exebacase during the period of performance under the contract will be funded in part with federal funds from HHS; ASPR; BARDA, under contract number 75A501212C00021.

Forward-Looking Statements

This press release contains, and our officers and representatives may make from time to time, “forward-looking statements” within the meaning of the U.S. federal securities laws. Forward-looking statements can be identified by words such as “projects,” “may,” “will,” “could,” “would,” “should,” “believes,” “expects,” “anticipates,” “estimates,” “intends,” “plans,” “potential,” “promise” or similar references to future periods. Examples of forward-looking statements in this release include, without limitation, statements regarding: the positive execution of every portfolio program, manuscripts, data, study patient enrollment and expected timelines, timing of the interim futility analysis, in vivo and in vitro results, presentations and publications, the Company’s financial results, financial position, balance sheets and statements of operations, ContraFect’s ability to discover and develop DLAs as new medical modalities for the treatment of life-threatening, antibiotic-resistant infections, whether ContraFect will address life-threatening infections using its DLA platform, whether exebacase has the potential to be a first-in-class treatment for *Staph aureus* bacteremia, the features, properties and potential utility of CF-370 and whether it will advance towards an IND submission, whether lysins are a new class of DLAs which are recombinantly produced, antimicrobial proteins with a novel mechanism of action associated with the rapid killing of target bacteria, eradication of biofilms and synergy with conventional antibiotics, whether amurins are a novel class of DLAs which exhibit broad-spectrum activity against a wide range of antibiotic-resistant Gram-negative pathogens, and whether the properties of ContraFect’s lysins and amurins will make them suitable for targeting antibiotic-resistant organisms, such as MRSA and *P. aeruginosa*. Forward-looking statements are statements that are not historical facts, nor assurances of future performance. Instead, they are based on ContraFect’s current beliefs, expectations and assumptions regarding the future of its business, future plans, strategies, projections, anticipated events and trends, the economy and other future conditions. Because forward-looking statements relate to the future, they are subject to inherent risks, uncertainties and changes in circumstances that are difficult to predict and many of which are beyond ContraFect’s control, including the occurrence of any adverse events related to the discovery, development and commercialization of ContraFect’s product candidates such as unfavorable clinical trial results, insufficient supplies of drug products, the lack of regulatory approval, or the unsuccessful attainment or maintenance of patent protection and other important risks detailed under the caption “Risk Factors” in ContraFect’s filings with the Securities and Exchange Commission. Actual results may differ from those set forth in the forward-looking statements. Important factors that could cause actual results to differ include, among others, our ability to develop treatments for drug-

resistant infectious diseases. Any forward-looking statement made by ContraFect in this press release is based only on information currently available and speaks only as of the date on which it is made. Except as required by applicable law, ContraFect expressly disclaims any obligations to publicly update any forward-looking statements, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

CONTRAFECT CORPORATION
Condensed Balance Sheets

(in thousands, except share and per-share data)

	June 30, 2021	December 31, 2020
	(unaudited)	(audited)
Assets		
Current assets:		
Cash and cash equivalents	\$ 21,406	\$ 15,485
Short-term marketable securities	46,093	27,005
Prepaid expenses and other current assets	8,533	4,165
	76,032	46,655
Total current assets	76,032	46,655
Long-term marketable securities	7,161	—
Property and equipment, net	827	910
Operating lease right-of-use assets	2,682	2,811
Other assets	105	740
	86,807	51,116
Total assets	\$ 86,807	\$ 51,116
Liabilities and stockholders' equity		
Current liabilities	7,960	6,060
Warrant liabilities	18,552	29,404
Long-term portion of lease liabilities	2,788	2,959
Other liabilities	73	73
	29,373	38,496
Total liabilities	29,373	38,496
Total stockholders' equity	57,434	12,620
	86,807	51,116
Total liabilities and stockholders' equity	\$ 86,807	\$ 51,116

CONTRAFECT CORPORATION
Unaudited Statements of Operations

(in thousands, except share and per-share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	\$ 7,777	\$ 5,544	\$ 15,798	\$ 10,648
General and administrative	2,935	2,619	5,700	5,579
Total operating expenses	10,712	8,163	21,498	16,227
Loss from operations	(10,712)	(8,163)	(21,498)	(16,227)
Other income (expense):				
Interest income	30	26	55	95
Other expense	—	(2,175)	—	(2,175)
Change in fair value of warrant liabilities	5,286	(7,305)	10,852	(6,889)
Total other income (expense), net	5,316	(9,454)	10,907	(8,969)
Net (loss)	\$ (5,396)	\$ (17,617)	\$ (10,591)	\$ (25,196)
Per share information:				
Basic and diluted net loss per share	\$ (0.14)	\$ (0.88)	\$ (0.31)	\$ (1.43)
Shares used in computing net loss per share	39,332,721	19,991,894	34,176,801	17,661,968

In this release, management has presented its financial position as of June 30, 2021 and its operating results for the three and six months ended June 30, 2021 and 2020 in accordance with U.S. Generally Accepted Accounting Principles (GAAP). The Company's financial position as of December 31, 2020 has been extracted from the Company's audited financial statements included in its Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 30, 2021. You should refer to both the Company's Quarterly Report on Form 10-Q and its Annual Report on Form 10-K for a complete discussion of financial information.

Investor Relations Contacts

Michael Messinger
ContraFect Corporation
mmessinger@contrafect.com



Source: ContraFect Corporation