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ContraFect Reports Third Quarter 2020 Financial Results and Provides Business Update

CARB-X and Cystic Fibrosis Foundation grants provide significant additional funding to advance CF-370 for Pseudomonas aeruginosa infections

Initiated expanded access program with exebacase for the treatment of persistent MRSA bloodstream infections in COVID-19 patients

YONKERS, New York, Nov. 13, 2020 (GLOBE NEWSWIRE) -- [ContraFect Corporation \(Nasdaq: CFRX\)](#) a 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 third quarter ended September 30, 2020.

“We are pleased with the progress of the Phase 3 DISRUPT superiority study of exebacase, which received Breakthrough Therapy designation from the FDA earlier this year, in patients suffering from life-threatening *Staph aureus* bloodstream infections,” said Roger J. Pomerantz, M.D., President, Chief Executive Officer, and Chairman of ContraFect. “We also continue to advance our pipeline programs towards the clinic and appreciate the tremendous financial support from CARB-X and the Cystic Fibrosis Foundation for our second product candidate, CF-370, an engineered lysin targeting *Pseudomonas aeruginosa*.”

Q3 2020 Highlights and Recent Developments

- In October, ContraFect initiated an expanded access program to provide exebacase for the treatment of persistent bacteremia caused by methicillin-resistant *Staphylococcus aureus* (MRSA) in COVID-19 patients. The Company is providing expanded access to exebacase under a treatment protocol available to clinical sites participating in the ongoing Phase 3 study, which enables physicians to use exebacase to treat severely ill COVID-19 patients with persistent MRSA bacteremia, despite treatment with standard of care antibiotics. Hospitalized patients with COVID-19 may now have access to exebacase since they are not eligible to participate in the ongoing Phase 3 study.
- In August, the Company entered into an agreement with the Cystic Fibrosis Foundation

to investigate the potential utility of DLAs against resistant Gram-negative pathogens which afflict Cystic Fibrosis (CF) patients. The first stage of the agreement will provide funding for the *in vitro* characterization of the activity of CF-370, an engineered lysin targeting *Pseudomonas aeruginosa*, and selected amurin peptides, against bacterial specimens obtained from CF patients at different stages of disease. With supportive data, ContraFect plans to evaluate future clinical development of CF-370 and/or amurin peptides as potential therapeutics for the treatment of pulmonary exacerbations in CF patients.

- In July, the Company announced that CARB-X (Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator), a global non-profit partnership dedicated to accelerating antibacterial research and development, awarded the Company up to \$18.9 million in additional non-dilutive capital to progress CF-370 through IND-enabling activities toward Phase 1 clinical trials. The award provides initial funding of \$4.9 million, and ContraFect could receive additional funding at the discretion of CARB-X if certain project milestones are met.

Ongoing COVID-19 Response

- The Phase 3 DISRUPT (Direct Lysis of *Staph aureus* Resistant Pathogen Trial) study of exebacase is ongoing. The Company continues to enroll patients and open new clinical trial sites across the United States. The study continues to experience some delays in patient enrollment due to the diversion of healthcare resources resulting from the COVID-19 pandemic in certain high impact areas.

Third Quarter 2020 Financial Results

- Research and development (R&D) expenses were \$4.7 million for the third quarter of 2020 compared to \$5.3 million in the comparable period in 2019. This decrease was primarily attributable to a decrease in internal and external research costs and a decrease in chemistry, manufacturing and controls (CMC) activities in the current quarter. These decreases were partially offset by increases in CRO expenses, clinical headcount and related personnel costs and professional fees to support the ongoing Phase 3 clinical study of exebacase.
- General and administrative (G&A) expenses were \$2.6 million for the third quarter of 2020 compared to \$2.4 million in the comparable period in 2019. This increase was primarily attributable to increases in professional fees and insurance costs.
- GAAP net income was \$3.4 million, or \$0.12 per share, for the third quarter of 2020 compared to a GAAP net loss of \$5.4 million, or \$0.67 per share, for the comparable period in 2019. After adjustment for the dilutive impact of the change in fair value of certain warrant liabilities, the Company reported a net loss of \$5.4 million, or \$0.19 per diluted share, for the third quarter of 2020.
- As of September 30, 2020, ContraFect had cash, cash equivalents and marketable securities of \$50.2 million.

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 on top of standard-of-care (SOC) antibiotics was nearly 43-percentage points higher than in patients treated with SOC antibiotics alone (74.1% for patients treated with exebacase and SOC antibiotics, 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 mean length of hospital stay and meaningful reductions in 30-day 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 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 SOC antibiotics. The primary efficacy endpoint of the study is clinical response at day 14 in patients with MRSA bacteremia, including right-sided endocarditis. 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. The company plans to conduct an interim futility analysis following the enrollment of approximately 60% of the study population.

About ContraFect:

ContraFect is a 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. 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 *Pseudomonas aeruginosa* (*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 in adult patients.

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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 significance of the CARB-X and Cystic Fibrosis Foundation (CFF) grants and whether they will advance CF-370, whether the expanded access program was initiated, ContraFect’s ability to discover and develop DLAs as new medical modalities for the treatment of life-threatening, antibiotic-resistant infections, statements made by Dr. Pomerantz, whether physicians will use exebacase to treat severely ill COVID-19 patients, whether hospitalized COVID-19 patients will have access to exebacase, whether the Company will obtain supportive data using CFF funding and be able to evaluate future clinical development of CF-370 or amurin peptides as potential therapeutics for the treatment of pulmonary exacerbations in CF patients, whether the Company receives all initial and additional CARB-X funding, statements made regarding how COVID-19 has effected the Phase 3 DISRUPT study, statements made regarding the Phase 2 study results, the Company’s financial results, financial position, balance sheets and statements of operations, statements made regarding the Phase 3 study and whether the Company will conduct an interim futility analysis, whether exebacase has the potential to be a first-in-class treatment for exebacase, whether ContraFect will address life-threatening infections using its DLA platform, 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 those 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

	September 30, 2020	December 31, 2019
	(unaudited)	(audited)
Assets		
Current assets:		
Cash and cash equivalents	\$ 18,152,046	\$ 24,184,140
Marketable securities	32,082,709	—
Prepaid expenses and other current assets	5,828,086	6,575,375
Total current assets	56,062,841	30,759,515
Property and equipment, net	957,587	1,099,948
Operating lease right-of-use assets	2,870,431	3,043,826
Other assets	105,420	105,420
Total assets	\$ 59,996,279	\$ 35,008,709
Liabilities and stockholders' equity		
Current liabilities	4,828,382	10,057,950
Warrant liabilities	33,659,991	6,068,978
Long-term portion of lease liabilities	3,038,056	3,264,128
Other liabilities	72,747	72,747
Total liabilities	41,599,176	19,463,803
Total stockholders' equity	18,397,103	15,544,906
Total liabilities and stockholders' equity	\$ 59,996,279	\$ 35,008,709

CONTRAFECT CORPORATION
Unaudited Statements of Operations

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Operating expenses:				
Research and development	\$ 4,706,012	\$ 5,250,327	\$ 15,354,453	\$ 14,161,543

General and administrative	2,607,472	2,376,248	8,186,169	7,234,244
Total operating expenses	<u>7,313,484</u>	<u>7,626,575</u>	<u>23,540,622</u>	<u>21,395,787</u>
Loss from operations	(7,313,484)	(7,626,575)	(23,540,622)	(21,395,787)
Other income (expense):				
Interest income	58,451	80,747	154,019	334,307
Other income (expense)	9,609	—	(2,165,044)	—
Change in fair value of warrant liabilities	<u>10,689,855</u>	<u>2,186,710</u>	<u>3,800,356</u>	<u>18,622,471</u>
Total other income (expense)	<u>10,757,915</u>	<u>2,267,457</u>	<u>1,789,331</u>	<u>18,956,778</u>
Net income (loss)	<u>\$ 3,444,431</u>	<u>\$ (5,359,118)</u>	<u>\$ (21,751,291)</u>	<u>\$ (2,439,009)</u>
Per share information:				
Basic net income (loss) per share	<u>\$ 0.12</u>	<u>\$ (0.67)</u>	<u>\$ (1.03)</u>	<u>\$ (0.31)</u>
Shares used in computing basic net income (loss) per share	<u>27,809,169</u>	<u>7,940,931</u>	<u>21,069,057</u>	<u>7,940,931</u>
Diluted net loss per share	<u>\$ (0.19)</u>	<u>\$ (0.67)</u>	<u>\$ (1.03)</u>	<u>\$ (0.31)</u>
Shares used in computing diluted net loss per share	<u>29,079,107</u>	<u>7,940,931</u>	<u>21,069,057</u>	<u>7,940,931</u>

The Company's financial position as of September 30, 2020 and results of operations for the three and nine months ended September 30, 2020 and 2019 have been extracted from the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission. The Company's financial position as of December 31, 2019 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 18, 2020. 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.

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Source: ContraFect Corporation