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): February 24, 2020

ContraFect Corporation
(Exact name of registrant as specified in its charter)

Delaware	001-36577	39-2072586
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification Number)

28 Wells Avenue, 3rd Floor, Yonkers, New York 10701
(Address of principal executive offices) (Zip Code)

(914) 207-2300
Registrant's telephone number, including area code

N/A
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation 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, $0.0001 par value per share	**CFRX**	**Nasdaq Capital 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 February 24, 2020, ContraFect Corporation (the "Company") issued a press release announcing that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy designation for exebacase for the treatment of MRSA bacteremia, including right-sided endocarditis, when used in addition to standard-of-care anti-staphylococcal antibiotics in adult patients.The full text of the press release issued in connection with this announcement is filed as Exhibit 99.1 to this Form 8-K.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release issued on February 24, 2020

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.

CONTRAFECT CORPORATION

Date: February 24, 2020

By: /s/ Natalie Bogdanos
Natalie Bogdanos
General Counsel and Corporate Secretary

Exhibit 99.1

ContraFect Announces U.S. FDA Grants Breakthrough Therapy Designation to Exebacase for the Treatment of Methicillin-Resistant *Staphylococcus aureus* (MRSA) Bacteremia, Including Right-Sided Endocarditis

YONKERS, New York — February 24, 2020 — **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 that that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy designation to exebacase for the treatment of MRSA bloodstream infections (bacteremia), including right-sided endocarditis, when used in addition to standard-of-care (SOC) anti-staphylococcal antibiotics in adult patients.

Breakthrough Therapy designation is a program designed by the FDA to expedite the development and review of medicines for serious or life-threatening diseases with preliminary clinical evidence that the investigational therapy may demonstrate substantial improvement on at least one clinically significant endpoint over available therapies.

“Since 1958, when vancomycin was first approved, only one additional agent has gained FDA approval for the treatment of MRSA bacteremia, based on non-inferiority to vancomycin. Despite this new agent, clinical failure and mortality rates for this neglected infectious disease have not improved in over 60 years.” said Roger J. Pomerantz, MD, President, Chief Executive Officer, and Chairman of ContraFect. “The decision by the FDA to grant Breakthrough Therapy designation to exebacase recognizes the urgent need for new therapies that can impact the lives of patients with these MRSA infections. Based on the Phase 2 data, we believe exebacase could be the first anti-infective agent to demonstrate superior outcomes for these patients.”

The Breakthrough Therapy designation was based on final data from a Phase 2 superiority trial of exebacase in patients with *Staphylococcus aureus* bacteremia, including endocarditis. This Phase 2 trial evaluated whether the addition of exebacase to SOC antibiotic therapy improved clinical response rates compared to treatment with SOC antibitotics alone. In a pre-specified analysis of the subgroup with MRSA infections, the clinical responder rate at Day 14 among exebacase-treated patients was 42.8 percentage points higher than the responder rate among patients treated with SOC antibiotics alone (74.1% vs 31.3%, respectively, p=0.010). Treatment with exebacase was also associated with a 21-percentage point reduction in the 30-day all-cause mortality (p=0.056), a four day reduction in length of hospital stay, and meaningful reductions in 30-day hospital readmission rates in MRSA-infected patients.

“I’m thrilled that the FDA has granted Breakthrough Therapy designation for exebacase for the treatment of MRSA bacteremia, a difficult to treat infection with consistently poor outcomes despite conventional antibiotics. In our Phase 2 study, the addition of exebacase to standard-of-care antibiotics to treat MRSA bacteremia was associated with higher clinical success rates and a reduction in mortality,” said Cara Cassino, MD, Chief Medical Officer and Executive Vice President of Research and Development at ContraFect. “We designed the pivotal Phase 3 DISRUPT study of exebacase for the treatment of *Staph aureus* bacteremia, including right-sided endocarditis, to enable definitive confirmation of these findings. Based on our interactions with the FDA regarding streamlined development of exebacase, this single Phase 3 study, in addition to the full package of data generated to date, may serve as the basis of a Biologics License Application for FDA review and potential approval of exebacase. We look forward to continuing to work closely with the FDA to expedite the development of this promising product candidate.”

About DISRUPT:

DISRUPT is an ongoing, randomized, double-blind, placebo-controlled, multi-center Phase 3 clinical study of exebacase for the treatment of *Staph aureus* bacteremia, including right-sided endocarditis, caused by MRSA or methicillin-senstitive *Staph aureus*. This study compares the efficacy, safety and tolerability of exebacase used in addition to SOC antibiotics to SOC antibiotics alone. The Company expects to enroll approximately 350 patients randomized 2:1 to receive either a single dose of exebacase administered as a 2-hour IV infusion in addition to SOC antibiotics or placebo plus SOC antibiotics. The primary efficacy endpoint will be clinical response at Day 14 in patients with MRSA bacteremia, including right-sided endocarditis. Secondary endpoints will include clinical response at Day 14 in All Staph aureus patients (MRSA and MSSA), 30-day all-cause mortality in MRSA patients, and clinical response at Day 30 and Day 60 in both MRSA and All Staph aureus patients. The principal investigator is Dr. Vance Fowler, Professor of Medicine in the Division of Infectious Diseases at Duke University.

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. Exebacase has the potential to be a first-in-class treatment for *Staph aureus* bacteremia. It has a novel, rapid, and specific mechanism of action that targets the peptidoglycan cell wall that is vital to *Staph aureus* bacteria. In addition, in vitro and in vivo experiments have shown that exebacase is highly active against biofilms which complicate *Staph aureus* infections. Exebacase was licensed from The Rockefeller University and is being developed at ContraFect.

About ContraFect:

ContraFect is a biotechnology company focused on discovering and developing differentiated biologic therapies for life-threatening, drug-resistant infectious diseases, particularly those treated in hospital settings. 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 new class of DLAs, which exhibit broad-spectrum activity against a wide range of antibiotic-resistant Gram-negative pathogens, including *Pseudomonas 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.

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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 ContraFect's ability to discover and develop DLAs as new medical modalities for the treatment of life-threatening, antibiotic-resistant infections, statements made regarding MRSA treatment, the Breakthrough Therapy process and the basis for its grant, comments made by Dr. Pomerantz and Dr. Cassino, Phase 2 results, Phase 3 study design and plans, the potential for exebacase to be a first-in-class treatment for *Staph aureus* bacteremia, ContraFect's ability to 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 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.

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