
**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): May 14, 2021

ContraFect Corporation

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-36577
(Commission
File Number)

39-2072586
(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 2.02. Results of Operations and Financial Condition.

On May 14, 2021, ContraFect Corporation announced its financial results for the quarter ended March 31, 2021. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Form 8-K (including Exhibit 99.1) shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly provided by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

The following exhibit relating to Item 2.02 shall be deemed to be furnished, and not filed:

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release issued on May 14, 2021

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.

Date: May 14, 2021

CONTRAFECT CORPORATION

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



ContraFect Reports First Quarter 2021 Financial Results and Provides Business Update

Interim futility analysis from the Phase 3 DISRUPT study of exebacase evaluating treatment superiority is anticipated in H2 2021

BARDA contract award provides up to \$86.8 million for exebacase development

Strong financial position with cash and investments of \$87.2 million as of March 31, 2021

YONKERS, New York — May 14, 2021 — 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 first quarter ended March 31, 2021.

“After an excellent first quarter of 2021, during which we received a considerable contract award from BARDA to support the continued late-stage development of exebacase, we remain focused on patient enrollment in the Phase 3 DISRUPT superiority study of exebacase and advancement of our earlier stage product candidates. We also continue building the foundation for ContraFect’s leadership in bringing forward truly novel classes of potential therapeutics with the promise of providing superior clinical outcomes to existing standard of care approaches for the treatment of life-threatening and highly resistant bacterial infections,” said Roger J. Pomerantz, M.D., President, Chief Executive Officer, and Chairman of ContraFect.

Q1 2021 Highlights and Recent Developments

- ContraFect continues to expand its senior team with individuals who bring deep and diverse industry experience to the Company: David Wilfret, M.D., Vice President of Clinical Development, Elsie DiBella, Ph.D., Vice President of Manufacturing and Development, Nancy Capra, Vice President of Program Management and Development Operations, and Brittany La, Esq., Assistant General Counsel.
- In April 2021, ContraFect announced that the United States Patent and Trademark Office issued U.S. Patent No. 10,988,520 (the ‘520 patent) for composition of matter of CF-370, the company’s second potential therapeutic product candidate. The ‘520 patent, which is owned solely by ContraFect, expires in March of 2039, and is the latest U.S. patent to issue from the Company’s DLA patent portfolio.
- In March 2021, ContraFect closed an underwritten public offering of 11,500,000 shares of its common stock at a public offering price of \$5.00 per share, including the full exercise of the underwriters’ option to purchase additional shares. The net proceeds from the offering were approximately \$53.8 million.

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- In March 2021, ContraFect announced that it had entered into a cost-share contract with Biomedical Advanced Research and Development Authority (BARDA), part of the Office of the Assistant Secretary for Preparedness and Response (ASPR) at the U.S. Department of Health and Human Services (HHS). Under the terms of contract number 75A501212C00021, the Company will receive \$9.8 million in initial funding and is eligible for up to an additional \$77.0 million. The initial funding will be used to support ContraFect's ongoing pivotal Phase 3 DISRUPT (Direct Lysis of *Staph aureus* Resistant Pathogen Trial) superiority study of exebacase in patients with *Staph aureus* bacteremia, including right-sided endocarditis. Under the terms of the agreement, and if supported by Phase 3 DISRUPT study data, BARDA may provide the Company with the additional funding upon achievement of key milestones to continue the advancement of exebacase through FDA product approval and completion of post-approval commitments.
 - In February 2021, ContraFect announced the appointment of Jane F. Barlow, MD, MPH, MBA to the Company's board of directors. Dr. Barlow is an expert in drug launch readiness and pricing, and is currently the Chief Executive Officer of Jane Barlow & Associates, LLC, Executive Vice President and Chief Clinical Officer at Real Endpoints. She is a senior advisor to MIT's Center for Biomedical Innovation and serves on the Biotech Advisory Board of Pictet Asset Management. Prior to her current roles, she was Associate Chief Medical Officer at CVS Health and Chief Medical Officer of CVS Health's Government Services. Dr. Barlow previously served on the boards of Momenta Pharmaceuticals, Inc. (prior to and during its sale to Johnson and Johnson), TherapeuticsMD Inc., and SilverScript Insurance Company.

First Quarter and 2021 Financial Results

- Research and development expenses were \$8.0 million for the first quarter of 2021 compared to \$5.1 million in the comparable period in 2020. This increase was primarily attributable to increases in expenditures on clinical activities for enrollment of patients and expansion of clinical sites in the Phase 3 DISRUPT study of exebacase, spending on non-clinical studies of CF-370 and our other preclinical programs, and expenditures for the additional headcount supporting the continued progress across the Company's portfolio.
- General and administrative expenses were \$2.8 million for the first quarter of 2021 compared to \$3.0 million in the comparable period in 2020. This decrease was due primarily to a decrease in costs incurred for intellectual property and general corporate legal fees.
- Net loss was \$5.2 million, or a loss of \$0.18 per share, for the first quarter of 2021 compared to net loss of \$7.6 million, or a loss of \$0.49 per share, for the comparable period in 2020. The decrease in net loss per share includes a \$5.2 million, or \$0.18 per share, increase in the non-cash gain for the change in fair value of warrant liabilities.
- As of March 31, 2021, ContraFect had cash, cash equivalents and marketable securities of \$87.2 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*, including hospital-acquired and ventilator-associated pneumonias and pulmonary exacerbations of cystic fibrosis.

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 in adult patients.

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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: timing of the interim futility analysis, expected receipt and use of BARDA funding, 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, 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)

	March 31, 2021 (unaudited)	December 31, 2020 (audited)
Assets		
Current assets:		
Cash and cash equivalents	\$ 65,246	\$ 15,485
Short-term marketable securities	20,904	27,005
Prepaid expenses and other current assets	5,089	4,165
Total current assets	91,239	46,655
Long-term marketable securities	1,030	—
Property and equipment, net	874	910
Operating lease right-of-use assets	2,747	2,811
Other assets	740	740
Total assets	<u>\$ 96,630</u>	<u>\$ 51,116</u>
Liabilities and stockholders' equity		
Current liabilities	7,940	6,060
Warrant liabilities	23,837	29,404
Long-term portion of lease liabilities	2,875	2,959
Other liabilities	73	73
Total liabilities	34,725	38,496
Total stockholders' equity	61,905	12,620
Total liabilities and stockholders' equity	<u>\$ 96,630</u>	<u>\$ 51,116</u>

CONTRAFECT CORPORATION
Unaudited Consolidated Statements of Operations

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

	Three Months Ended March 31,	
	2021	2020
Operating expenses		
Research and development	\$ 8,021	\$ 5,104
General and administrative	2,765	2,960
Total operating expenses	10,786	8,064
Loss from operations	(10,786)	(8,064)
Other income:		
Interest income	24	70
Change in fair value of warrant liabilities	5,567	416
Total other income	5,591	486
Net loss	<u>\$ (5,195)</u>	<u>\$ (7,578)</u>
Per share information:		
Net loss per share of common stock, basic and diluted	<u>\$ (0.18)</u>	<u>\$ (0.49)</u>
Basic and diluted weighted average shares outstanding	<u>28,963,594</u>	<u>15,332,042</u>

In this release, management has presented its financial position as of March 31, 2021 and its operating results for the first quarters of 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.

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