
**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 16, 2022

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 16, 2022, ContraFect Corporation announced its financial results for the quarter ended March 31, 2022. 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 16, 2022
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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 16, 2022

CONTRAFECT CORPORATION

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



ContraFect Reports First Quarter 2022 Financial Results and Provides Business Update

Phase 3 DISRUPT study achieves enrollment of MRSA patients necessary for DSMB to conduct interim futility analysis

YONKERS, New York – May 16, 2022 — **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, 2022.

“I am very pleased to announce that we have eclipsed the enrollment threshold, meaning over 60% of the methicillin-resistant *Staph aureus* (MRSA) patients, needed for the interim futility analysis of our Phase 3 DISRUPT study to be conducted and we currently have about two-thirds of the entire study population enrolled as well. I want to thank our entire team for their hard work and tremendous persistence to achieve these milestones during the pandemic,” said Roger J. Pomerantz, M.D., ContraFect’s President, Chief Executive Officer, and Chairman. “Now we turn our attention to the interim futility analysis, which, unlike other analyses for non-inferiority endpoints, will enable the Data Safety Monitoring Board, or DSMB, to assess the probability for exebacase to achieve superiority on the primary efficacy endpoint of the study. Once the data necessary for this analysis is collected, processed and delivered to the DSMB, we will be informed of their recommendation regarding study continuation. We expect this to occur during the first week of July. We are extremely eager to get the recommendation of the DSMB, and, if positive, pivot with alacrity towards building our organization to support potential BLA submission, approval and commercialization of this new modality therapeutic.”

First Quarter 2022 Highlights and Recent Developments

- ContraFect expanded its senior team with the promotion of Matthew Salamone, SPHR, PHR to Vice President of Human Resources who will support the anticipated growth and development of the Company through the upcoming key milestones.
- In April 2022, the Company provided an oral presentation at the 32nd European Congress of Clinical Microbiology & Infectious Diseases (ECCMID) Annual Meeting of new data from an *in vivo* efficacy study of CF-370 in a rabbit acute pneumonia model caused by an extensively drug-resistant (XDR) *Pseudomonas aeruginosa* (*P. aeruginosa*). Multiple dose regimens of CF-370 administered alone and in addition to amikacin, demonstrated statistically significant reductions of bacteria counts in the lungs as compared to amikacin alone and vehicle controls. Statistically significant reductions of bacteria counts in secondary organs of interest, the spleen and the kidney, were also seen when CF-370 was administered in addition to amikacin compared to the administration of amikacin alone.

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- In April 2022, ContraFect presented multiple posters at the 32nd ECCMID Annual Meeting characterizing the susceptibility profile of CF-370. Utilizing the standard 28-day serial passage method to induce *in vitro* resistance, CF-370 demonstrated an extremely low propensity for developing decreased susceptibility to the Gram-negative ESKAPE pathogens (*P. aeruginosa*, *Acinetobacter baumannii*, *Klebsiella pneumoniae* and *Enterobacter cloacae*) as well as other deadly Gram-negative pathogens – *Escherichia Coli*, *Stenotrophomonas maltophilia*, and *Achromobacter xylosoxidans*. Furthermore, CF-370 also demonstrated the ability to suppress *in vitro* resistance of *P. aeruginosa* to current standard of care antibiotics – meropenem, tobramycin and levofloxacin.
 - In January 2022, the Company received its second contract award from the Cystic Fibrosis Foundation. This contract award will support *in vitro* and *in vivo* investigations of the potential utility of exebacase for treating cystic fibrosis (CF) lung infections caused by MRSA. The program will expand and augment the positive data from the *in vitro* characterization of the activity of CF-370 and selected amurin peptides against bacterial specimens obtained from CF patients under the first award.

First Quarter 2022 Financial Results

- Research and development expense was \$12.7 million for the first quarter of 2022 compared to \$8.0 million in the comparable period in 2021. This increase was primarily attributable to an increase in spending on manufacturing costs related to the process transfer, analytical and process validation, and manufacturing of exebacase that will support a potential BLA submission and on clinical activities as we continued to enroll patients and expand the number of clinical sites in the Phase 3 DISRUPT study of exebacase. These increases were partially offset by a decrease in spending on non-clinical studies of CF-370 and our other preclinical programs.
- General and administrative expense was \$3.3 million for the first quarter of 2022 compared to \$2.8 million in the comparable period in 2021. This was due primarily to an increase in costs for personnel and related expenses.
- Net loss was \$20.2 million, or a loss of \$(0.51) per share, for the first quarter of 2022 compared to a net loss of \$5.2 million, or a loss of \$(0.18) per share, for the comparable period in 2021. The net loss per share in the current period includes a \$4.2 million, or \$0.11 per share, non-cash charge 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 \$5.6 million, or \$0.19 per share, non-cash gain from the change in the fair value of the Company's warrant liabilities.
- As of March 31, 2022, ContraFect had cash, cash equivalents and marketable securities of \$42.3 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 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 was well-tolerated and treatment emergent adverse events, including serious treatment-emergent serious adverse events (SAEs) were balanced between the treatment groups. There were no SAEs determined to be related to exebacase, there were no reports of hypersensitivity related to exebacase and no patients discontinued treatment with study drug in either treatment group.

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. The lysin 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 and consequently unable to work in vitro in human blood or in animal models. However, based on the proprietary methods the Company has identified and utilizes to engineer lysins, CF-370 has exhibited the hallmark in vitro microbiologic attributes of the lysin class, including rapid and potent bactericidal activity, synergy with a broad range of standard of care agents 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 highly resistant strains of *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 development as a 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: Phase 3 study patient enrollment, the interim futility analysis, the study data necessary for the analysis, 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, timing of the interim futility analysis and whether the DSMB will conduct the same, the DSMB recommendation, whether the Company will be able to pivot towards supporting a BLA submission, approval and commercialization of exebacase, whether the Company will grow and develop through key milestones, statements made regarding the Cystic Fibrosis Foundation award, the Company’s financial results, financial position, balance sheets and statements of operations, exebacase and CF-370 attributes, the potential therapeutic utility of CF-370, whether ContraFect will address life-threatening infections using therapeutic candidates from 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)

	March 31, 2022 <u>(unaudited)</u>	December 31, 2021 <u>(audited)</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 9,637	\$ 16,654
Marketable securities	32,644	37,631
Prepaid expenses	6,541	4,439
Other current assets	3,450	4,140
Total current assets	52,272	62,864
Property and equipment, net	696	741
Operating lease right-of-use assets	2,471	2,544
Other assets	601	613
Total assets	<u>\$ 56,040</u>	<u>\$ 66,762</u>
Liabilities and stockholders' equity		
Current liabilities	\$ 16,714	\$ 12,174
Warrant liabilities	6,742	2,530
Long-term portion of lease liabilities	2,513	2,609
Other liabilities	73	73
Total liabilities	26,042	17,386
Total stockholders' equity	29,998	49,376
Total liabilities and stockholders' equity	<u>\$ 56,040</u>	<u>\$ 66,762</u>

CONTRAFECT CORPORATION
Unaudited Statements of Operations

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

	Three Months Ended March 31,	
	2022	2021
Operating expenses		
Research and development	\$ 12,725	\$ 8,021
General and administrative	3,254	2,765
Total operating expenses	<u>15,979</u>	<u>10,786</u>
Loss from operations	(15,979)	(10,786)

	Three Months Ended March 31,	
	2022	2021
Other income:		
Interest income	34	24
Change in fair value of warrant liabilities	(4,212)	5,567
Total other income	(4,178)	5,591
Net loss	<u>\$ (20,157)</u>	<u>\$ (5,195)</u>
Per share information:		
Net loss per share of common stock, basic and diluted	<u>\$ (0.51)</u>	<u>\$ (0.18)</u>
Basic and diluted weighted average shares outstanding	<u>39,332,721</u>	<u>28,963,594</u>

In this release, management has presented its financial position as of March 31, 2022 and its operating results for the first quarters of 2022 and 2021 in accordance with U.S. Generally Accepted Accounting Principles (GAAP). The Company's financial position as of December 31, 2021 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 25, 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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