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): March 24, 2022

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 2.02. Results of Operations and Financial Condition.

On March 24, 2022, ContraFect Corporation announced its financial results for the fourth quarter and fiscal year ended December 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:

Exhibit No.	Description
99.1	Press Release issued on March 24, 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.

CONTRAFECT CORPORATION

Date: March 24, 2022

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

ContraFect Reports Fourth Quarter 2021 and Full Year 2021 Financial Results and Provides Business Update

Phase 3 DISRUPT study enrollment continues on course towards conducting interim futility analysis as anticipated in H1 2022

YONKERS, New York – March 24, 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 announces business updates and financial results for the fourth quarter and full year ended December 31, 2021.

"Most importantly, we are on track and continue to expect to conduct the planned interim futility analysis based on approximately 60% of the MRSA study population by the end of the first half of 2022. Unlike other analyses for non-inferiority, this analysis will assess the probability for exebacase to achieve superiority on the primary efficacy endpoint over standard-of-care antibiotics alone," said Roger J. Pomerantz, M.D., ContraFect's President, Chief Executive Officer, and Chairman. "In addition, we look forward to the continued execution of our ongoing early and late stage preclinical pipeline programs for some of the most resistant bacterial pathogens, and to providing updates as they become available."

Fourth Quarter 2021 Highlights and Recent Developments

- In January 2022, the Company received its second contract award from the Cystic Fibrosis Foundation. This contract award will support investigation of the potential utility of exebacase for treating serious lung infections caused by methicillin-resistant *Staphylococcus aureus* (MRSA) in people with cystic fibrosis (CF). The program, titled *Nonclinical Assessment of Lysin Exebacase for Treating MRSA Infections in CF* will, over the course of approximately 12 months, evaluate the *in vitro* activity of exebacase against bacterial specimens obtained from CF patients.
- In December 2021, a case study report was published in *Clinical Infectious Diseases*, a journal of the Infectious Disease Society of America (IDSA), highlighting the potential of exebacase to treat MRSA bacteremia in a pediatric population. The patient, a previously healthy 5-month-old male infant, presented to Duke University Hospital for evaluation of jerking movements and inability to sit independently. Following a full evaluation, it was determined that he had blood culture confirmed MRSA infection with life-threatening multi-organ involvement, affecting the brain (left temporal subdural empyema), upper airway (a retropharyngeal abscess), and heart (right-sided endocarditis). Despite targeted antibiotic therapy, optimized dosing, and attempts at source control, clearance of bacteremia and clinical improvement was not achieved with standard of care (SOC) antibiotics alone. The treating physician obtained authorization from the U.S. Food and Drug Administration (FDA) to use exebacase under an emergency individual patient

investigational new drug application and the patient subsequently received one 3 mg dose of exebacase on hospital day 7. The patient continued to receive SOC anti-staphylococcal antibiotics throughout the hospital stay. Blood cultures became sterile on hospital day 12. The patient had ongoing clinical improvement and serial echocardiograms noted no evidence of heart valve vegetation on hospital day 40. The patient was discharged, without the need for additional surgery.

- In October 2021, the Company presented important new data at IDWeek 2021, in a late breaker, oral presentation, from the Phase 2 study of exebacase. These data demonstrated that exebacase, used in addition to standard-of-care antibiotics (SOCA), more rapidly resolved clinical symptoms of *Staph aureus* bacteremia versus SOCA alone. The median time to resolution was 3 days for exebacase-treated patients, as compared to 6 days for SOCA-alone patients. Notably, among the exebacase-treated patients with MRSA bacteremia, the median time to symptom resolution was 3 days, as compared to 7 days in patients who received SOCA alone. Additionally, 94.1% of exebacase-treated patients with MRSA bacteremia showed symptom resolution, compared with only 81.8% MRSA bacteremia patients treated with SOCA alone.
- In October 2021, new microbiologic surveillance data was presented at IDWeek 2021 on the *in vitro* activity of exebacase against *Staph aureus* clinical isolates causing bacteremia in the United States, including multidrug-resistant (MDR) strains. The data showed that *Staph aureus* accounted for approximately 25% of all pathogens recovered from blood specimens and nearly 40% of *Staph aureus* infected samples were of a methicillin-resistant phenotype. These data demonstrated the potent activity of exebacase and that its activity was consistent, regardless of resistance phenotype (MSSA, MRSA, including MDR isolates).
- In October 2021, the Company presented new data on the activity of DLAs against the most prevalent MDR pathogenic Gram-negative strains responsible for pulmonary infections in CF patients at the North American Cystic Fibrosis Conference. The data further support the *in vitro* activity profile of CF-370 and amurin AM1 against specific Gram-negative pathogens, including *Pseudomonas aeruginosa (P. aeruginosa)*, *Stenotrophomonas maltophilia*, and *Achromobacte*r spp.

Fourth Quarter 2021 Financial Results

- Research and development (R&D) expenses were $11.0 million for the fourth quarter of 2021 compared to $7.3 million in the comparable period in 2020. This increase was primarily attributable to increases in expenditures on contract research organizations (CROs) to support the active enrollment of patients in the Phase 3 DISRUPT study of exebacase, and on contract manufacturers to complete the process transfer of, and progress the validation of, the exebacase manufacturing process to support the chemistry, manufacturing and controls (CMC) activities required for potential BLA submission for exebacase. The manufacturing process for CF-370 has also moved forward towards enabling an Investigational New Drug (IND) application later this year. Finally, the Company increased its clinical development and CMC headcount and related personnel costs to support the continued advancement of its programs across the pipeline. These increases were partially offset by an increase in the reimbursement of expenses under the Company’s BARDA contract and grants compared to the prior year period.

- R&D expenses were $35.5 million for the year ended December 31, 2021, compared to $22.6 million for the year ended December 31, 2020. This increase was primarily attributable to increases in expenditures for the Phase 3 DISRUPT study of exebacase as we increased patient enrollment and expanded the number of clinical sites, for the manufacturing costs related to the process transfer, ongoing process validation and manufacturing of exebacase and for the expansion of the Company's internal research, clinical development and CMC teams. These increases were partially offset by an increase in the reimbursement of expenses under the Company's contract with BARDA and various grants compared to the prior year period.
- General and administrative (G&A) expenses were $3.0. million for the fourth quarter of 2021 compared to $3.4 million in the comparable period in 2020. This decrease was primarily attributable to decreases in legal expenses and recruiting costs.
- G&A expenses were $11.8 million for the year ended December 31, 2021, compared with $11.6 million for the year ended December 31, 2020. This increase was primarily attributable to the increase in insurance costs.
- Net loss was $4.4 million, or a loss of $(0.11) per share, for the fourth quarter of 2021 compared to net loss of $6.4 million, or a loss of $(0.23) per share, for the comparable period in 2020. The net loss in the current period includes a $9.7 million, or $0.25 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 included a $4.3 million, or $0.15 per share, non-cash gain from the change in the fair value of the Company's warrant liabilities.
- Net loss was $20.3 million, or a loss of $(0.55) per share, for the year ended December 31, 2021 compared to net loss of $28.2 million, or a loss of $(1.24) per share, for the year ended December 31, 2020. The net loss for the current year period includes a $26.9 million, or $0.73 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 included an $8.1 million, or $0.35 per share, non-cash gain from the change in the fair value of the Company's warrant liabilities. The net loss per share was also impacted by the year-over-year increase in the weighted average shares outstanding.
- As of December 31, 2021, ContraFect had cash, cash equivalents and marketable securities of $54.3 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 SOCA alone (74.1% for patients treated with exebacase compared to 31.3% for patients treated with SOCA 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 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 SOCA. 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. An independent Data Safety Monitoring Board (DSMB) will conduct the interim futility analysis after 60% of the MRSA population (the primary endpoint study population) completes the Day 14 primary endpoint study visit.

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 SOCA 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: Phase 3 study enrollment, timing of the interim futility analysis and whether it will be conducted in H1 2022, 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, the Company's ability to provide updates on pipeline programs, the Company's financial results, financial position, balance sheets and statements of operations, ContraFect's ability to 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, the potential therapeutic utility of CF-370, 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)

	December 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 16,654	$ 15,485
Marketable securities	37,631	27,005
Prepaid expenses	4,439	3,084
Other current assets	4,140	1,081
Total current assets	62,864	46,655
Property and equipment, net	741	910
Operating lease right-of-use assets	2,544	2,811
Other assets	613	740
Total assets	$ 66,762	$ 51,116
Liabilities and stockholders' equity		
Current liabilities	$ 12,174	$ 6,060
Warrant liabilities	2,530	29,404
Long-term portion of lease liabilities	2,609	2,959
Other liabilities	73	73
Total liabilities	17,386	38,496
Total stockholders' equity	49,376	12,620
Total liabilities and stockholders' equity	$ 66,762	$ 51,116

CONTRAFECT CORPORATION
Statements of Operations
(in thousands, except share and per-share data)

	Three Months Ended December 31,		Year Ended December 31,	
	2021	2020	2021	2020
	(unaudited)	(unaudited)		
Operating expenses:				
Research and development	$ 11,048	$ 7,260	$ 35,508	$ 22,614
General and administrative	3,033	3,439	11,757	11,625
Total operating expenses	14,081	10,699	47,265	34,239
Loss from operations	(14,081)	(10,699)	(47,265)	(34,239)
Other income (expense):				
Interest income	18	39	109	192
Other income (expense)	–	–	–	(2,165)
Change in fair value of warrant liabilities	9,664	4,256	26,874	8,056
Total other income	9,682	4,295	26,983	6,083
Net loss	$ (4,339)	$ (6,404)	$(20,282)	$(28,156)

(in thousands, except share and per-share data)	Three Months Ended December 31,		Year Ended December 31,	
	2021	2020	2021	2020
Per share information:				
Net loss per share of common stock, basic and diluted	$ (0.11)	$ (0.23)	$ (0.55)	$ (1.24)
Basic and diluted weighted average shares outstanding	39,332,721	27,810,102	36,775,950	22,763,528

In this release, management has presented its financial position as of December 31, 2021 and its operating results for the three months and years ended December 31, 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 Annual Report on Form 10-K for a complete discussion of financial information.

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