
**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): August 15, 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 August 15, 2022, ContraFect Corporation announced its financial results for the quarter ended June 30, 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 August 15, 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: August 15, 2022

CONTRAFECT CORPORATION

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



ContraFect Reports Second Quarter 2022 Financial Results and Provides Corporate Update

Focused on advancement of lead programs, exebacase and CF-370, into new clinical studies

YONKERS, New York – August 15, 2022 — **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 second quarter ended June 30, 2022.

“Despite the recent setback from the interim futility analysis of our Phase 3 DISRUPT superiority study of intravenous (IV) exebacase, we continue to advance our lead programs toward new clinical studies. We expect to file with regulatory authorities later this year to initiate a study of intra-articular exebacase in patients with chronic or recurrent prosthetic joint infections. We believe this patient population provides the best opportunity now for exebacase to again demonstrate proof of concept, as well as to differentiate this molecule from the current, surgical standard of care treatment. We are also completing the GLP toxicology studies required for the IND application of CF-370, for resistant gram-negative infections. We currently expect to advance CF-370 into clinical development with a multiple day dose regimen aimed at maximizing its opportunity to demonstrate clinical efficacy,” said Roger J. Pomerantz, M.D., President, Chief Executive Officer, and Chairman of ContraFect. “The needs of patients with deadly and debilitating resistant bacterial infections demand that we continue to move our product candidates forward to establish a potential new treatment modality for these patients, their families and their physicians,” added Dr. Pomerantz.

Corporate Strategy

In order to be positioned to initiate the potential clinical trials discussed above, the Company has taken multiple actions to maximize its resources and focus its efforts on the execution of its corporate strategy. Subsequent to the Data Safety Monitoring Board (“DSMB”) recommendation, disclosed in the Company’s press release issued and 8-K filed with the Securities and Exchange Commission (“SEC”) on July 13, 2022, that the Phase 3 DISRUPT (Direct Lysis of Staph aureus Resistant Pathogen Trial) trial be stopped for futility, the Company has implemented the following actions:

- The Company initiated and has completed a significant portion of its own analyses of the accrued DISRUPT study data and expects to complete the analysis toward the end of the third quarter of 2022. The Company expects that conclusions drawn from the ongoing data review will inform next steps for any potential further development of exebacase.

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- Investigators were notified of the DSMB recommendation and that new patient enrollment in the trials was being stopped. The Company expects the final patients already enrolled in the study at the time of the DSMB recommendation to complete their follow-up visits in September. The Company also expects to complete all clinical study reports as required by the FDA.
 - All CMC (chemistry, manufacturing and controls) activities related to the potential commercialization of IV exebacase have been or are in the process of being suspended.
 - The Company has reduced its workforce by 16 employees, or approximately 37% of the Company's headcount as of June 30, 2022. The Company expects to recognize a restructuring charge in the third quarter of 2022 of approximately \$1.5 million consisting primarily of severance, one-time termination and other related costs, all of which will result in future cash expenditures. The Company expects this headcount reduction to lower its annual operating costs by over \$4.0 million. This reduction includes the resignation of Cara Cassino, M.D. as Chief Medical Officer and Executive Vice President of Research and Development of the Company. Dr. Cassino's resignation as an officer of the Company was effective on August 14, 2022. The Company thanks Dr. Cassino for her years of dedication and for remaining with the Company through August 31, 2022 to transition the role and for continuing to serve as a valued consultant after the transition.
 - Finally, the Company has engaged Garrett Nichols, M.D., M.S., to be its Interim Chief Medical Officer. With more than 20 years in the life sciences industry, Dr. Nichols brings vast experience managing the global development efforts of multiple infectious disease and cancer therapeutics at both small and large, biopharmaceutical companies. Dr. Nichols earned his M.D. from Duke University and his M.S. in epidemiology from the University of Washington, where he also completed a fellowship in infectious diseases. The Company welcomes Dr. Nichols into the organization to assist with the potential advancement of exebacase and CF-370 into new clinical trials.

Recent Corporate Highlights

- In June 2022, at the 2022 ASM Microbe Conference, the Company provided the results from a study evaluating the activity of exebacase or CF-296 in a preclinical rabbit model of implant-associated methicillin-resistant *Staphylococcus aureus* (MRSA) osteomyelitis which demonstrated that the local administration of either lysin to the affected bone, in addition to systemically administered daptomycin, resulted in significant reduction in MRSA counts on infected implants compared to daptomycin alone. Notably, the administration of exebacase alone, without systemic antibiotics, resulted in significant reductions in MRSA counts compared to controls. Further information about this study can be found by reading the manuscript published in the peer-reviewed Journal of Bone and Joint Infection.
- 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.

Second Quarter 2022 Financial Results

- Research and development (R&D) expense was \$16.8 million for the second quarter of 2022 compared to \$7.8 million in the comparable period in 2021. This increase was primarily attributable to an increase in spending on CMC costs related to the analytical and process validation and pre-commercial manufacturing of exebacase, an increase in spending on non-clinical studies of exebacase and IND-enabling studies of CF-370 to support a potential IND application, and an increase in spending on clinical activities as we continued to enroll patients and expand the number of clinical sites ahead of the interim futility analysis of the Phase 3 DISRUPT study of exebacase.
- General and administrative (G&A) expense was \$3.3 million for the second quarter of 2022 compared to \$2.9 million in the comparable period in 2021. This was due primarily to an increase in costs for personnel and related expenses.
- Net loss was \$18.1 million, or a loss of \$0.46 per share, for the second quarter of 2022 compared to net loss of \$5.4 million, or a loss of \$0.14 per share, for the comparable period in 2021. The net loss per share in the current period includes a \$1.9 million, or \$0.05 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 per share included a \$5.3 million, or \$0.13 per share, non-cash gain from the change in the fair value of the Company's warrant liabilities.
- As of June 30, 2022, ContraFect had cash, cash equivalents and marketable securities of \$27.3 million.

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 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 further details as to how ContraFect intends to proceed with the development of exebacase and the ongoing analysis of the data sets from the Phase 3 clinical study of exebacase, timing and expectations surrounding regulatory submissions and initiation of potential clinical trials, statements made by Dr. Pomerantz, expectations surrounding the workforce reduction, ContraFect’s corporate strategy, ContraFect’s ability to discover and develop DLAs as new medical modalities for the treatment of life-threatening, antibiotic-resistant infections, 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, without limitation, that ContraFect has and expects to continue to incur significant losses, ContraFect’s need for additional funding, which may not be available, 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, changes in management may negatively affect ContraFect's business and other important risks detailed under the caption "Risk Factors" in ContraFect's Quarterly Report on Form 10-Q for the quarter ended June 30, 2022 and its other filings with the Securities and Exchange Commission. Actual results may differ from those set forth in the forward-looking statements. 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)

	June 30, 2022 (unaudited)	December 31, 2021 (audited)
Assets		
Current assets:		
Cash and cash equivalents	\$ 9,549	\$ 16,654
Marketable securities	17,753	37,631
Prepaid expenses	8,313	4,439
Other current assets	2,097	4,140
Total current assets	37,712	62,864
Property and equipment, net	653	741
Operating lease right-of-use assets	2,326	2,544
Other assets	107	613
Total assets	<u>\$ 40,798</u>	<u>\$ 66,762</u>
Liabilities and stockholders' equity		
Current liabilities		
Warrant liabilities	\$ 20,600	\$ 12,174
Long-term portion of lease liabilities	4,826	2,530
Other liabilities	2,414	2,609
Other liabilities	73	73
Total liabilities	27,913	17,386
Total stockholders' equity	12,885	49,376
Total liabilities and stockholders' equity	<u>\$ 40,798</u>	<u>\$ 66,762</u>

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

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2022</u>	<u>2021</u>	<u>2022</u>	<u>2021</u>
Operating expenses:				
Research and development	\$ 16,760	\$ 7,777	\$ 29,485	\$ 15,798
General and administrative	3,266	2,935	6,520	5,700
Total operating expenses	<u>20,026</u>	<u>10,712</u>	<u>36,005</u>	<u>21,498</u>
Loss from operations	(20,026)	(10,712)	(36,005)	(21,498)
Other (expense) income:				
Interest income	21	30	55	55
Change in fair value of warrant liabilities	1,916	5,286	(2,296)	10,852
Total other (expense) income, net	<u>1,937</u>	<u>5,316</u>	<u>(2,241)</u>	<u>10,907</u>
Net loss	<u>\$ (18,089)</u>	<u>\$ (5,396)</u>	<u>\$ (38,246)</u>	<u>\$ (10,591)</u>
Per share information:				
Basic and diluted net loss per share	<u>\$ (0.46)</u>	<u>\$ (0.14)</u>	<u>\$ (0.97)</u>	<u>\$ (0.31)</u>
Shares used in computing net loss per share	<u>39,332,721</u>	<u>39,332,721</u>	<u>39,332,721</u>	<u>34,176,801</u>

In this release, management has presented its financial position as of June 30, 2022 and its operating results for the three and six months ended June 30, 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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