
**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): November 14, 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 November 14, 2022, ContraFect Corporation announced its financial results for the quarter ended September 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.

Item 8.01. Other Events

The Company has recently engaged in discussions with certain investors to explore a potential equity financing in the form of an offering of its securities. After evaluating the investors' proposal, the Company has elected not to move forward under the terms of their proposal. The Company will continue to evaluate financing and other strategic opportunities as it considers its cash needs and business outlook.

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 November 14, 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: November 14, 2022

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



ContraFect Reports Third Quarter 2022 Financial Results and Provides Corporate Update

Continued execution to advance exebacase and CF-370 into new clinical studies

YONKERS, New York – November 14, 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 third quarter ended September 30, 2022.

“I am quite proud of our team at ContraFect, as we worked through significant, unexpected adversity while continuing to successfully execute on our near-term objectives. We submitted a CTA to ANSM, the French regulatory agency, to begin a Phase 1b/2 clinical study of intra-articular exebacase in patients with chronic prosthetic joint infections of the knee. In addition, we completed the GLP toxicology studies of CF-370, our lysin for the potential treatment of important Gram-negative infections, including resistant *Pseudomonas*, *Acinetobacter* and *Klebsiella*, and expect to submit an IND for CF-370 by the end of the first quarter of 2023. We also completed the patient monitoring and follow-up of the final patients of the DISRUPT study and look to achieve database lock in December. We expect to communicate the results from the full study population in the first half of 2023 and from our own analysis of the futility analysis dataset shortly after database lock, or earlier if possible,” said Roger J. Pomerantz, M.D., President, Chief Executive Officer, and Chairman of ContraFect. “We are excited about 2023 and the prospect of having two different programs in the clinic, with the potential to demonstrate that we can significantly improve clinical outcomes for patients suffering from deadly and debilitating resistant bacterial infections,” added Dr. Pomerantz.

Third Quarter 2022 Highlights and Recent Developments

- In October 2022, the Company’s Clinical Trial Authorization (CTA) submission to Agence nationale de sécurité du médicament et des produits de santé (ANSM), the French National Agency for the Safety of Medicines and Health Products, for the study of intra-articular exebacase in patients with chronic prosthetic joint infections of the knee due to *S. aureus* or coagulase-negative Staphylococci (CoNS) was accepted for review. Assuming approval of the submission by ANSM, the Company expects to begin dosing patients in the first quarter of 2023.
- In October 2022, at IDWeek 2022, the Company provided a poster presentation of new clinical data from a single center, exploratory, open-label prospective study using the minimally invasive LysinDAIR procedure (lysin administration during an arthroscopic DAIR procedure) in patients with suspected

relapsing chronic CoNS prosthetic hip infection (PHI). At two years follow up, all patients had resolution of fistula and no clinical signs of infection. The LysinDAIR procedure was easy-to-perform, safe and demonstrated the therapeutic potential of exebacase to facilitate the success of salvage therapy for chronic relapsing CoNS PJIs and to cure initial chronic PJIs. The poster can be found on the Company's [website](#).

- In September 2022, at the 40th Annual Meeting of the European Bone and Joint Infection Society, Dr. Tristan Ferry of the Infectious and Tropical Diseases Unit, Croix-Rousse Hospital, Hôpices Civils de Lyon in Lyon, France provided an oral presentation of new clinical data from a single center, exploratory, open-label prospective study using a minimally invasive LysinDAIR procedure in patients with chronic knee PJI, due to CoNS, with two different clinical presentations and treatment paradigms. The first cohort included patients suffering their first episode of CoNS knee PJI. The LysinDAIR procedure was followed by three months of clindamycin and levofloxacin. Through follow up periods of up to 36 months, the patients have experienced no relapse of infection, no recurrence of the joint effusion and no loosening of the prostheses. The second cohort included patients suffering from a complex episode of multi-drug resistant CoNS knee PJI. The LysinDAIR procedure was followed by three months of antibiotics plus additional suppressive antimicrobial therapy. Two patients, through follow up periods of up to 12 months, have experienced no relapse of infection, no recurrence of the joint effusion and no loosening of the prostheses. One patient experienced a relapse of infection of *Staphylococcus caprae* after six months. One patient died from an unrelated COVID-19 infection. Exebacase was well tolerated by all patients. No local or systemic serious adverse events (SAEs) related to exebacase were reported.
- In September 2022, the Company announced two publications. The first, an editorial in the [Journal of Bone and Joint Infection](#), discussed the potential for lysins to become advantageous agents in the treatment armamentarium against bone and joint infections (BJIs) compared with current antibiotic treatments alone based on the *in vitro* activity of lysins seen against CoNS, the bacteria most frequently involved in implant-associated BJIs, and the potential for both local and systemic anti-biofilm activity. The second article, published in [Antimicrobial Agents and Chemotherapy](#), a leading peer reviewed journal dedicated to the study of treatments for infectious diseases, presented the results demonstrating such *in vitro* activity of exebacase against biofilms isolated from patients with PJIs formed by clinical strains of *Staphylococcus epidermidis* (*S. epidermidis*), a CoNS species. Exebacase displayed significant anti-biomass and bactericidal activity against *S. epidermidis* biofilms, as well as synergistic effects in addition to rifampicin, vancomycin, and daptomycin.
- In August 2022, ContraFect announced the publication of a manuscript in the [Journal of Bone and Joint Infection](#) presenting the results from a study evaluating the activity of exebacase or the CF-296 lysin in a preclinical rabbit model of implant-associated methicillin-resistant *Staphylococcus aureus* (MRSA) osteomyelitis. The results demonstrated that the local administration of either lysin to the affected bone, in addition to systemic antibiotics, reduced MRSA counts in the bone and on implants compared with control animals. Notably, the administration of exebacase alone, without systemic antibiotics, resulted in significant reductions in MRSA counts compared to controls. Furthermore, when used in addition to systemically administered daptomycin, either lysin also resulted in significant reduction in MRSA counts on infected implants compared to daptomycin alone.

Third Quarter 2022 Financial Results

- Research and development (R&D) expense was \$10.8 million for the third quarter of 2022 compared to \$8.7 million in the comparable period in 2021. This increase was primarily attributable to an increase in spending on clinical activities as the Company stopped enrollment of patients in the Phase 3 DISRUPT study of exebacase and continued patient follow-up procedures and monitoring and an increase in spending on non-clinical studies of CF-370 to support a potential IND application and the completion of ongoing non-clinical studies of exebacase. A decrease in the reimbursable expenditures under the Company's grants and BARDA contract also contributed to the increase. These increases were partially offset by a decrease in manufacturing expenses due to the suspension of CMC activities related to the potential commercialization of exebacase, a decrease in spending on development personnel as a result of the Company's restructuring plan and decrease in external research expenditures on other discovery programs.
- General and administrative (G&A) expense was \$3.4 million for the third quarter of 2022 compared to \$3.0 million in the comparable period in 2021. This was due primarily to an increase in legal fees and stock-based compensation expense.
- Restructuring expense was \$7.7 million for the third quarter of 2022 compared to no expense in the comparable period in 2021. The restructuring plan announced during the quarter was designed to reduce costs and align resources with the Company's anticipated product development milestones for exebacase and CF-370 and to help preserve the value of the Company's drug discovery operations. This expense was comprised of employee termination costs, including severance, health benefits and other related expenses from a workforce reduction and a write-off of prepaid manufacturing costs.
- Net loss was \$17.1 million, or a loss of \$0.43 per share, for the third quarter of 2022 compared to net loss of \$5.3 million, or a loss of \$0.13 per share, for the comparable period in 2021. The net loss per share in the current period includes a \$4.8 million, or \$0.12 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 \$6.4 million, or \$0.16 per share, non-cash gain from the change in the fair value of the Company's warrant liabilities.
- As of September 30, 2022, ContraFect had cash, cash equivalents and marketable securities of \$17.6 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 the continued advancement of exebacase and CF-370, whether the company will execute near-term objectives, the ongoing analysis of the data sets from the Phase 3 clinical study of exebacase, timing and expectations surrounding: the ANSM CTA submission, initiation of patient dosing in the Phase 1b/2 clinical study, CF-370 tox studies, the CF-370 IND submission, and DISRUPT study activities including: database lock, patient monitoring and follow-up, analysis of results and communication of those results, statements made by Dr. Pomerantz, whether the company can significantly improve clinical outcomes for patients suffering from deadly and debilitating resistant bacterial infections 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 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 September 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)

	September 30, 2022 <u>(unaudited)</u>	December 31, 2021 <u>(audited)</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 4,664	\$ 16,654
Marketable securities	12,984	37,631
Prepaid expenses	1,815	4,439
Other current assets	586	4,140
Total current assets	20,049	62,864
Property and equipment, net	628	741
Operating lease right-of-use assets	2,249	2,544
Other assets	108	613
Total assets	<u>\$ 23,034</u>	<u>\$ 66,762</u>
Liabilities and stockholders’ (deficit) equity		
Current liabilities		
Warrant liabilities	\$ 23,783	\$ 12,174
Long-term portion of lease liabilities	3	2,530
Other liabilities	2,313	2,609
Other liabilities	38	73
Total liabilities	26,137	17,386
Total stockholders’ (deficit) equity	(3,013)	49,376
Total liabilities and stockholders’ (deficit) equity	<u>\$ 23,034</u>	<u>\$ 66,762</u>

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

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2022</u>	<u>2021</u>	<u>2022</u>	<u>2021</u>
Operating expenses:				
Research and development	\$ 10,814	\$ 8,664	\$ 40,299	\$ 24,462
General and administrative	3,366	3,022	9,886	8,722
Restructuring	7,719	—	7,719	—
Total operating expenses	<u>21,899</u>	<u>11,686</u>	<u>57,904</u>	<u>33,184</u>
Loss from operations	(21,899)	(11,686)	(57,904)	(33,184)
Other income:				
Interest income, net	9	36	64	91
Change in fair value of warrant liabilities	4,823	6,358	2,527	17,210
Total other income, net	<u>4,832</u>	<u>6,394</u>	<u>2,591</u>	<u>17,301</u>
Net loss	<u>\$ (17,067)</u>	<u>\$ (5,292)</u>	<u>\$ (55,313)</u>	<u>\$ (15,883)</u>
Per share information:				
Basic and diluted net loss per share	<u>\$ (0.43)</u>	<u>\$ (0.13)</u>	<u>\$ (1.41)</u>	<u>\$ (0.44)</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>35,914,327</u>

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