# 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 15, 2021**

# 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 November 15, 2021, ContraFect Corporation announced its financial results for the quarter ended September 30, 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 November 15, 2021. |
| 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 15, 2021

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

**Exhibit 99.1**

**ContraFect Reports Third Quarter 2021 Financial Results and Provides Corporate Update**

**YONKERS, New York — November 15, 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 third quarter ended September 30, 2021.

"We continue to make important progress across our extensive portfolio, as we generate and publish new and compelling data highlighting the potential meaningful improvements for patients that we have observed in a variety of difficult to treat infections. Our primary focus remains on the enrollment of patients in the Phase 3 DISRUPT superiority study of our Breakthrough Therapy, new modality drug, exebacase, in patients with *Staph aureus* bloodstream infections. We now have nearly 60 active clinical sites and we continue to accumulate patients every month, despite the ongoing COVID-19 pandemic. In addition, we remain vigilant in our financial management and will continue to provide our shareholders with relevant updates as they emerge," said Roger J. Pomerantz, M.D., President, Chief Executive Officer, and Chairman of ContraFect.

As previously communicated, the pandemic has caused some delays in patient enrollment during certain months of this year, as hospitals struggle to recover from the surges in COVID-19 infections and hospitalizations. ContraFect now expects to conduct the planned interim futility analysis to assess the superiority of exebacase versus standard of care antibiotics (SOCA) alone, based on approximately 60% of the MRSA study population, in the first half of 2022. The Company continues to anticipate completion of full patient enrollment for the study in 2022.

**Recent Corporate Highlights**

- In October, 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 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, new surveillance data was presented at IDWeek 2021 on the *in vitro* activity of exebacase against *Staph aureus* 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, ContraFect announced the poster presentation on the activity of DLAs against the most prevalent MDR pathogenic strains responsible for pulmonary infections in Cystic Fibrosis 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.
- In July, new data was presented at the 31st European Congress of Clinical Microbiology & Infectious Diseases (ECCMID) demonstrating the *in vitro* synergy for anti-biofilm activity of exebacase with either rifampin, vancomycin, or daptomycin against *Staph epidermidis* strains responsible for bone and joint infections of the knee, hip and shoulder. These data add to the evidence supporting the potential for exebacase to treat *Staph epidermidis* infections of prosthetic joints.
- In July, new data were presented at the 31st European Congress of Clinical Microbiology & Infectious Diseases (ECCMID) demonstrating the potent *in vitro* activity of CF-370 against clinical MDR and extreme drug-resistant (XDR) *P. aeruginosa* isolates, including carbapenem and colistin resistant forms. Isolates included those from the Centers for Disease Control Antibiotic Resistance Bank.

**Third Quarter 2021 Financial Results**

- Research and development (R&D) expenses were $8.7 million for the third quarter of 2021 compared to $4.7 million in the comparable period in 2020. This increase was primarily attributable to an increase in CRO and investigator site expenses related to the execution of the Phase 3 clinical study, an increase in expenditures for non-clinical studies of exebacase, CF-370, CF-296 and the amurin peptides, as all programs continued to progress forward, and an increase in clinical development and manufacturing headcount and related personnel costs to support the ongoing development of exebacase.
- General and administrative (G&A) expenses were $3.0 million for the third quarter of 2021 compared to $2.6 million in the comparable period in 2020. This increase was primarily attributable to an increase in administrative personnel and insurance costs, which was partially offset by a decrease in legal expenses.
- Net loss was $5.3 million, or a loss of $(0.13) per share, for the third quarter of 2021 compared to net income of $3.4 million, or income of $0.12 per share, for the comparable period in 2020. The net loss per share in the current period includes 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. In the prior year period, the net income per share included a $10.7 million, or $0.38 per share, non-cash gain from the change in the fair value of the Company's warrant liabilities.
- As of September 30, 2021, ContraFect had cash, cash equivalents and marketable securities of $63.3 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 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.*

**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: the Company's progress across its portfolio, data, study patient enrollment, delays and expected timelines, the disclosure of relevant updates, COVID-19, timing of the interim futility analysis, in vivo and in vitro results, presentations, 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, the features, properties and potential 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)**

| | September 30, 2021 (unaudited) | December 31, 2020 (audited) |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 20,225 | $ 15,485 |
| Marketable securities | 43,092 | 27,005 |
| Prepaid expenses and other current assets | 11,022 | 4,165 |
| Total current assets | 74,339 | 46,655 |
| Property and equipment, net | 784 | 910 |
| Operating lease right-of-use assets | 2,614 | 2,811 |
| Other assets | 105 | 740 |
| Total assets | $ 77,842 | $ 51,116 |
| **Liabilities and stockholders' equity** | | |
| Current liabilities | $ 9,869 | $ 6,060 |
| Warrant liabilities | 12,194 | 29,404 |
| Long-term portion of lease liabilities | 2,700 | 2,959 |
| Other liabilities | 73 | 73 |
| Total liabilities | 24,836 | 38,496 |
| Total stockholders' equity | 53,006 | 12,620 |
| Total liabilities and stockholders' equity | $ 77,842 | $ 51,116 |

**CONTRAFECT CORPORATION**
***Unaudited Statements of Operations***

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2021 | 2020 | 2021 | 2020 |
| Operating expenses: | | | | |
| Research and development | $ 8,664 | $ 4,706 | $ 24,462 | $ 15,354 |
| General and administrative | 3,022 | 2,607 | 8,722 | 8,186 |
| Total operating expenses | 11,686 | 7,313 | 33,184 | 23,540 |
| Loss from operations | (11,686) | (7,313) | (33,184) | (23,540) |
| Other income (expense): | | | | |
| Interest income | 36 | 58 | 91 | 154 |
| Other income (expense) | — | 10 | — | (2,165) |
| Change in fair value of warrant liabilities | 6,358 | 10,689 | 17,210 | 3,800 |
| Total other income | 6,394 | 10,757 | 17,301 | 1,789 |
| Net income (loss) | $ (5,292) | $ 3,444 | $(15,883) | $(21,751) |

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2021 | 2020 | 2021 | 2020 |
| Per share information: | | | | |
| Basic net income (loss) per share | $ (0.13) | $ 0.12 | $ (0.44) | $ (1.03) |
| Shares used in computing basic net income (loss) per share | 39,332,721 | 27,809,169 | 35,914,327 | 21,069,057 |
| Diluted net loss per share | $ (0.13) | $ (0.19) | $ (0.44) | $ (1.03) |
| Shares used in computing diluted net loss per share | 39,332,721 | 29,079,107 | 35,914,327 | 21,069,057 |

In this release, management has presented its financial position as of September 30, 2021 and its operating results for the three and nine months ended September 30, 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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