Zacks Small-Cap Research
*Sponsored – Impartial - Comprehensive*

March 16, 2021
David Bautz, PhD
312-265-9471
dbautz@zacks.com

scr.zacks.com
10 S. Riverside Plaza, Chicago, IL 60606

# ContraFect Corp.

## (CFRX-NASDAQ)

***CFRX: $86.8 Million BARDA Contract to Support Phase 3 Trial of Exebacase…***

Based on our updated probability adjusted DCF model that takes into account potential future revenues from CF-301 in bacteremia along with the lysin pipeline, we are increasing our valuation of CFRX to $25/share. This model is highly dependent upon continued clinical success of CF-301 and additional lysin products and will be adjusted accordingly based upon future clinical results.

| | |
|---|---|
| Current Price (03/16/21) | $6.14 |
| **Valuation** | **$25.00** |

## OUTLOOK

On March 11, 2021, ContraFect Corp. (CFRX) announced an $86.8 million contract with the Biomedical Advanced Research and Development Authority (BARDA) to support the ongoing Phase 3 DISRUPT trial of exebacase in patients with *Staphylococcus aureus* bacteremia, including right-sided endocarditis. The company will initially receive $9.8 million with up to an additional $77.0 million available upon the attainment of certain milestones. In addition, if supported by data from the DISRUPT trial, BARDA may provide additional support to advance exebacase through FDA approval and completion of post-approval commitments. We anticipate an interim analysis being performed once the first 60% of patients enrolled into the trial are evaluable for efficacy. At the current rate of enrollment, we estimate that will occur in the second half of 2021, with topline data for the full study population available in 2022. After factoring in the BARDA contract into our model, we are raising our valuation to $25 per share.

## SUMMARY DATA

| | |
|---|---|
| **52-Week High** | **$7.81** |
| **52-Week Low** | **$4.69** |
| **One-Year Return (%)** | **10.23** |
| **Beta** | **0.96** |
| **Average Daily Volume (sh)** | **1,421,407** |
| **Shares Outstanding (mil)** | **28** |
| **Market Capitalization ($mil)** | **$171** |
| **Short Interest Ratio (days)** | **N/A** |
| **Institutional Ownership (%)** | **60** |
| **Insider Ownership (%)** | **4** |
| **Annual Cash Dividend** | **$0.00** |
| **Dividend Yield (%)** | **0.00** |
| **5-Yr. Historical Growth Rates** | |
| **Sales (%)** | **N/A** |
| **Earnings Per Share (%)** | **N/A** |
| **Dividend (%)** | **N/A** |
| **P/E using TTM EPS** | **N/A** |
| **P/E using 2019 Estimate** | **-3.7** |
| **P/E using 2020 Estimate** | **-6.0** |

| | |
|---|---|
| **Risk Level** | **Above Avg.** |
| **Type of Stock** | **Small-Growth** |
| **Industry** | **Med-Drugs** |

## ZACKS ESTIMATES

**Revenue**
(in millions of $)

| | Q1 (Mar) | Q2 (Jun) | Q3 (Sep) | Q4 (Dec) | Year (Dec) |
|---|---|---|---|---|---|
| 2019 | 0 A | 0 A | 0 A | 0 A | 0 A |
| 2020 | 0 A | 0 A | 0 A | 0 E | 0 E |
| 2021 | | | | | 0 E |
| 2022 | | | | | 0 E |

**Earnings per Share**

| | Q1 (Mar) | Q2 (Jun) | Q3 (Sep) | Q4 (Dec) | Year (Dec) |
|---|---|---|---|---|---|
| 2019 | $1.46 A | -$1.09 A | -$0.67 A | -$1.11 A | -$1.54 A |
| 2020 | -$0.49 A | -$0.88 A | $0.12 A | -$0.28 E | -$1.30 E |
| 2021 | | | | | -$1.13 E |
| 2022 | | | | | -$1.03 E |

© Copyright 2021, Zacks Investment Research. All Rights Reserved.

## WHAT'S NEW

**Business Update**

*BARDA Contract to Support Development of Exebacase*

On March 11, 2021, ContraFect Corp. (CFRX) announced an $86.8 million contract with the Biomedical Advanced Research and Development Authority (BARDA) that will support the ongoing Phase 3 DISRUPT (Direct Lysis of *Staph aureus* Resistant Pathogen Trial) trial of exebacase in patients with *Staphylococcus aureus* bacteremia, including right-sided endocarditis. The company will receive an initial tranche of $9.8 million with up to $77.0 million in future support being dependent on progress and clinical success in the DISRUPT trial. Following completion of the trial, and assuming a positive outcome, the BARDA funding can be used to support additional development work that may be necessary for FDA approval, including manufacturing and regulatory activities. It could also cover any post-approval commitments, such as the completion of the pediatric study.

The DISRUPT trial is a randomized, double blind, placebo controlled study being conducted at over 40 centers in the U.S. and will enroll approximately 350 patients randomized 2:1 to receive either exebacase or placebo, with all patients receiving standard of care antibiotics. The ongoing coronavirus pandemic has resulted in a delay in patient enrollment due to hospitals struggling with an influx of COVID-19 patients in intensive care units. However, the rollout of highly effective COVID-19 vaccines should lead to a decrease in hospital burden as the year progresses and an increase in patient enrollment into the DISRUPT trial. A preplanned interim futility analysis is scheduled to take place after the first 60% of patients enrolled into the trial are evaluable for efficacy.

The primary endpoint of the trial is clinical response at Day 14 in patients with methicillin-resistant *S. aureus* (MRSA) bacteremia, including right-sided endocarditis. Clinical response is defined using objective clinical criteria including: 1) resolution of *S. aureus* bacteremia/right-sided endocarditis signs and symptoms that were present at baseline; 2) no new signs or symptoms of bacteremia/right-sided endocarditis; 3) no complications of bacteremia/right-sided endocarditis; 4) no changes in anti-staphylococcal antibiotics after treatment with study drug due to persistence, worsening, or recurrence of signs or symptoms of bacteremia/right-sided endocarditis; 5) blood cultures negative for *S. aureus* by Day 14; and 6) the patient is alive. Clinical response is being determined by an independent, blinded clinical adjudication committee.

Key secondary endpoints include clinical response rate at Day 14 for all *S. aureus* bacteremia patients (including both MRSA and methicillin-sensitive *S. aureus* [MSSA]), 30-day all-cause mortality in MRSA patients, and clinical response at Day 60. The company will also evaluate the impact of treatment with exebacase on length of hospital stay, length of stay in the intensive care unit, and 30-day readmission rates for both all-cause and *S. aureus* infection readmissions.

The following table shows the statistical parameters for the primary efficacy endpoint and key secondary efficacy endpoints from the trial. The primary endpoint is 86% powered to show a 28% increase in clinical response rate at Day 14 with the use of exebacase plus standard of care antibiotics compared to standard of care antibiotics alone.

| | Primary Efficacy Endpoint: Clinical Response at Day 14 (MRSA Patients) | Secondary Efficacy Endpoint: Clinical Response at Day 14 (All *Staph aureus* Patients) | Secondary Efficacy Endpoint: Mortality (MRSA Patients) |
|---|---|---|---|
| Target difference | 28% increase over SOC antibiotics alone | 16% increase over SOC antibiotics alone | 17% decrease from SOC antibiotics alone |
| Power | 86% | 83% | 80% |
| Sample size | 135 patients | 339 patients | 135 patients |

*Source*: ContraFect Corp.

*Longitudinal Study Shows Changes in Bacteremia Rates/Severity*

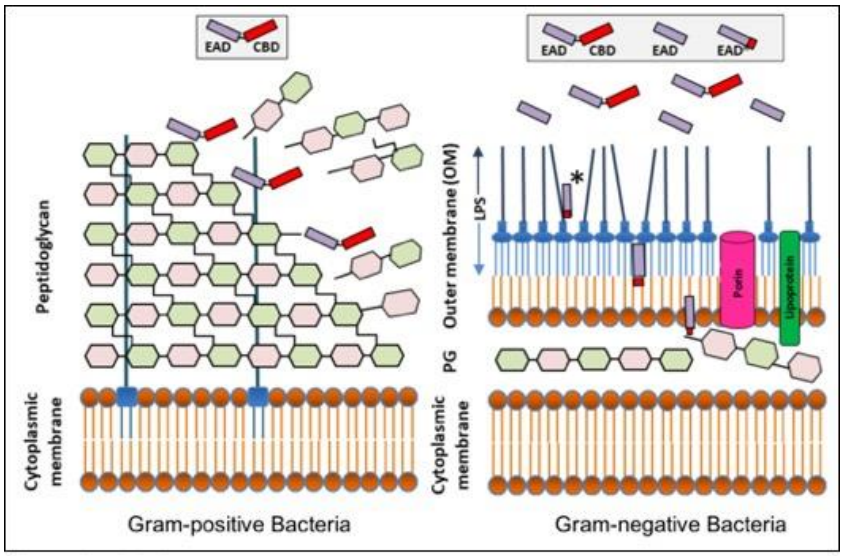
*S. aureus* bacteremia, including MRSA, is increasing in prevalence and severity. A 21-year longitudinal study of *S. aureus* bacteremia patients at Duke University Medical Center was conducted from January 1995 to December 2015 (Souli *et al*., 2019). A total of 2,348 unique patients were analyzed in the study and the initial *S. aureus* isolate was genotyped. During the study period, overall metastatic infections increased by 0.9% annually (*P*=0.019), which was driven by significant annual increases in abscesses, vertebral osteomyelitis, epidural abscesses, septic thrombophlebitis, endocarditis, and septic emboli. Of the 2,348 unique S. aureus isolates, 1,126 (48%) were MRSA.

A multivariate analysis showed that the USA300 strain was significantly associated with a higher risk for overall metastatic complications (OR 1.42, 95% CI 1.02–1.99), including septic emboli and persistent bacteremia even after for adjusting for variables such as age, gender, race, and comorbidities. USA300 was first identified in the 1990 and has quickly become the dominant MRSA strain in North America and the most common MRSA subtype isolated from bloodstream infections in some parts of the U.S. (Seybold *et al*., 2006; Diekema *et al*., 2014).

Another confounding factor noted during the study period was the overall decrease in health of patients in 2015 compared to 1995, including increased rates of various co-morbidities such as diabetes, cancer, transplantation, rheumatoid arthritis, and corticosteroid usage. Why patients with *S. aureus* bacteremia is unknown, but could be related to the increasing prevalence of those conditions, increasing life expectancy of patients suffering from those conditions, and/or increasing use of advanced procedures that predispose patients to *S. aureus* bacteremia. Regardless, patients with co-morbidities have an increased risk of negative outcomes associated with *S. aureus* bacteremia, particularly MRSA, and the increased incidence of high-risk co-morbidities underscores the notion that new and more effective treatment options are necessary for bacteremia patients.

*CF-370 Update*

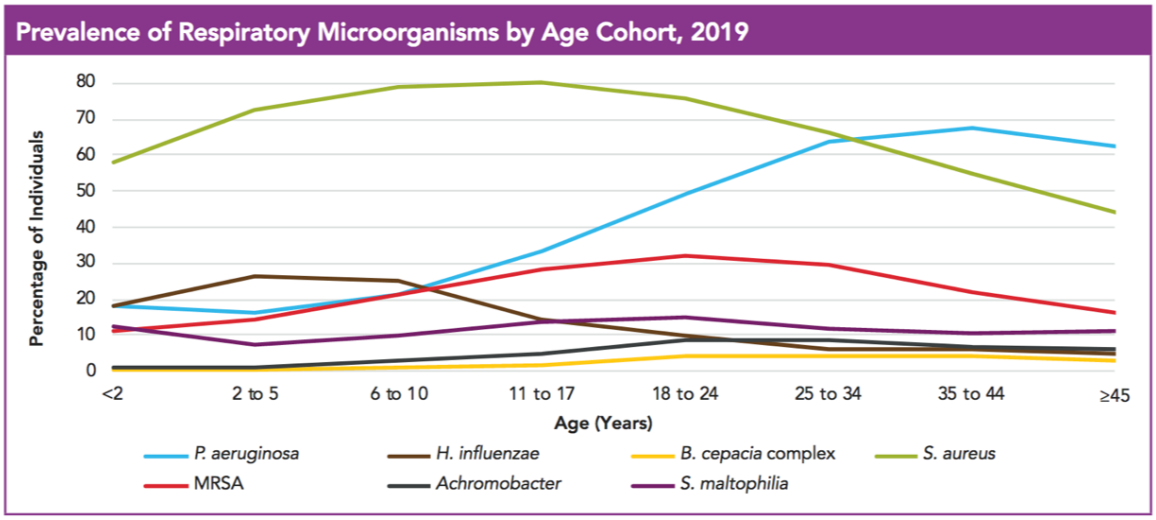
CF-370 is the company's lead engineered lysin development candidate targeting *Pseudomonas aeruginosa*, a Gram-negative bacterial species. The following figure shows how lysins are effective against Gram-positive bacteria due to their ability to easily interact with the peptidoglycan layer. However, Gram-negative bacteria have an outer membrane that acts as a barrier against most lysins, thus preventing them from reaching the peptidoglycan layer. While the majority of purified Gram-negative lysins have no antimicrobial activity, there are a select few that have some activity in low ionic strength buffers (indicated by the asterisk in the following figure on the right). It is these lysins that ContraFect used as lead compounds to modify in order to increase their anti-microbial activity, with CF-370 emerging as the lead candidate from this research.




*Source*: ContraFect Corp.

In mid-2020, ContraFect announced an award of up to $18.9 million from CARB-X (Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator), a global non-profit partnership dedicated to supporting the development of new antibacterial treatments, to support the IND-enabling activities for CF-370. The award is for an initial funding of $4.9 million, with additional funds dispersed based upon project milestones. IND-enabling studies are currently ongoing and we anticipate a Phase 1 trial initiating in the first half of 2022.

In addition, ContraFect also entered into an initial funding agreement with the Cystic Fibrosis Foundation to study the effect of using direct lytic agents against Gram-negative pathogens that commonly afflict cystic fibrosis (CF) patients. The following chart, derived from the 2019 Cystic Fibrosis Foundation Patient Registry, shows that *P. aeruginosa* makes up a considerable proportion of lung infections in CF patients, particularly as they get older. These infections are very difficult to treat, thus necessitating the need for improved therapeutics.




*Source*: CF Patient Registry, 2019

## Conclusion

The BARDA contract is a very important development for ContraFect as it will offer non-dilutive financing for the Phase 3 DISRUPT trial up to and through a BLA filing (assuming positive results) as well as for any required post-approval commitments. Funding from an agency such as BARDA is a nice validation of ContraFect's technology as those contracts are highly competitive and require sufficient evidence that a positive outcome is likely. We have incorporated the BARDA contract into our model, as it will result in less cash required for the exebacase program, along with advancing our model ahead one year, which has increased our valuation to $25 per share.

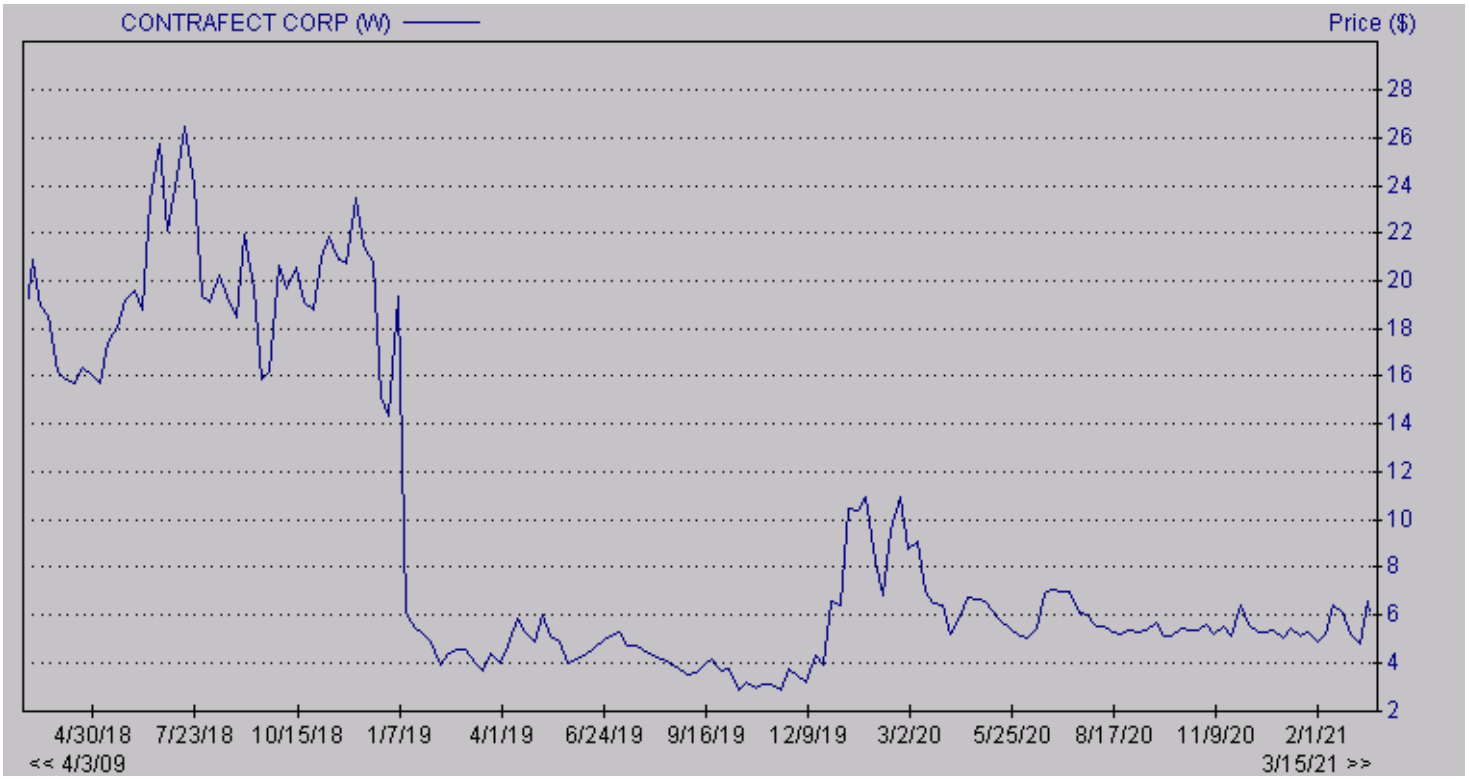
## PROJECTED FINANCIALS

| ContraFect Corp. | 2019 A | Q1 A | Q2 A | Q3 A | Q4 E | 2020 E | 2021 E | 2022 E |
|---|---|---|---|---|---|---|---|---|
| CF-301 (Bacteremia) | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 |
| *YOY Growth* | | - | - | - | - | | | |
| Grants & Collaborative Revenue | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 |
| *YOY Growth* | | - | - | - | - | | | |
| **Total Revenues** | **$0** | **$0** | **$0** | **$0** | **$0** | **$0** | **$0** | **$0** |
| *YOY Growth* | | - | - | - | - | | | |
| Cost of Sales | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 |
| *Product Gross Margin* | | - | - | - | - | | | |
| Research & Development | $18.1 | $5.1 | $5.5 | $4.7 | $5.0 | $20.4 | $21.0 | $23.0 |
| General & Administrative | $9.8 | $3.0 | $2.6 | $2.6 | $2.7 | $10.9 | $10.5 | $11.0 |
| Other Expenses | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 |
| Operating Income | ($27.9) | ($8.1) | ($8.2) | ($7.3) | ($7.7) | ($31.2) | ($31.5) | ($34.0) |
| *Operating Margin* | | - | - | - | - | | | |
| Non-Operating Expenses (Net) | $15.1 | $0.5 | ($9.5) | $10.8 | $0.0 | $1.8 | $0.0 | $0.0 |
| Pre-Tax Income | ($12.8) | ($7.6) | ($17.6) | $3.4 | ($7.7) | ($29.5) | ($31.5) | ($34.0) |
| Income Taxes Paid | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 |
| *Tax Rate* | *0%* | *0%* | *0%* | *0%* | *0%* | *0%* | *0%* | *0%* |
| **Net Income** | **($12.8)** | **($7.6)** | **($17.6)** | **$3.4** | **($7.7)** | **($29.5)** | **($31.5)** | **($34.0)** |
| *Net Margin* | | - | - | - | - | | | |
| **Reported EPS** | **($1.54)** | **($0.49)** | **($0.88)** | **$0.12** | **($0.28)** | **($1.30)** | **($1.13)** | **($1.03)** |
| *YOY Growth* | | - | - | - | - | | | |
| Basic Shares Outstanding | 8.3 | 15.3 | 20.0 | 27.8 | 27.8 | 22.7 | 27.8 | 33.0 |

*Source: Zacks Investment Research, Inc.* *David Bautz, PhD*

© Copyright 2021, Zacks Investment Research. All Rights Reserved.

## HISTORICAL STOCK PRICE




*Source*: Zacks Investment Research

© Copyright 2021, Zacks Investment Research. All Rights Reserved.

## DISCLOSURES

The following disclosures relate to relationships between Zacks Small-Cap Research ("Zacks SCR"), a division of Zacks Investment Research ("ZIR"), and the issuers covered by the Zacks SCR Analysts in the Small-Cap Universe.

ANALYST DISCLOSURES

I, David Bautz, PhD, hereby certify that the view expressed in this research report accurately reflect my personal views about the subject securities and issuers. I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the recommendations or views expressed in this research report. I believe the information used for the creation of this report has been obtained from sources I considered to be reliable, but I can neither guarantee nor represent the completeness or accuracy of the information herewith. Such information and the opinions expressed are subject to change without notice.

INVESTMENT BANKING AND FEES FOR SERVICES

Zacks SCR does not provide investment banking services nor has it received compensation for investment banking services from the issuers of the securities covered in this report or article.
Zacks SCR has received compensation from the issuer directly, from an investment manager, or from an investor relations consulting firm engaged by the issuer for providing non-investment banking services to this issuer and expects to receive additional compensation for such non-investment banking services provided to this issuer. The non-investment banking services provided to the issuer includes the preparation of this report, investor relations services, investment software, financial database analysis, organization of non-deal road shows, and attendance fees for conferences sponsored or co-sponsored by Zacks SCR. The fees for these services vary on a per-client basis and are subject to the number and types of services contracted. Fees typically range between ten thousand and fifty thousand dollars per annum. Details of fees paid by this issuer are available upon request.

POLICY DISCLOSURES

This report provides an objective valuation of the issuer today and expected valuations of the issuer at various future dates based on applying standard investment valuation methodologies to the revenue and EPS forecasts made by the SCR Analyst of the issuer's business.
SCR Analysts are restricted from holding or trading securities in the issuers that they cover. ZIR and Zacks SCR do not make a market in any security followed by SCR nor do they act as dealers in these securities. Each Zacks SCR Analyst has full discretion over the valuation of the issuer included in this report based on his or her own due diligence. SCR Analysts are paid based on the number of companies they cover. SCR Analyst compensation is not, was not, nor will be, directly or indirectly, related to the specific valuations or views expressed in any report or article.

ADDITIONAL INFORMATION

Additional information is available upon request. Zacks SCR reports and articles are based on data obtained from sources that it believes to be reliable, but are not guaranteed to be accurate nor do they purport to be complete. Because of individual financial or investment objectives and/or financial circumstances, this report or article should not be construed as advice designed to meet the particular investment needs of any investor. Investing involves risk. Any opinions expressed by Zacks SCR Analysts are subject to change without notice. Reports or articles or tweets are not to be construed as an offer or solicitation of an offer to buy or sell the securities herein mentioned.

CANADIAN COVERAGE

This research report is a product of Zacks SCR and prepared by a research analyst who is employed by or is a consultant to Zacks SCR. The research analyst preparing the research report is resident outside of Canada, and is not an associated person of any Canadian registered adviser and/or dealer. Therefore, the analyst is not subject to supervision by a Canadian registered adviser and/or dealer, and is not required to satisfy the regulatory licensing requirements of any Canadian provincial securities regulators, the Investment Industry Regulatory Organization of Canada and is not required to otherwise comply with Canadian rules or regulations.