Zacks Small-Cap Research
Sponsored – Impartial - Comprehensive

March 23, 2020
David Bautz, PhD
312-265-9471
dbautz@zacks.com

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

ContraFect Corp. (CFRX-NASDAQ)

CFRX: Interim Futility Analysis for Phase 3 DISRUPT Trial Once 60% Enrolled…

Based on our probability adjusted DCF model that takes into account potential future revenues from CF-301 in bacteremia along with the lysin pipeline, CFRX is valued at $30/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 (03/23/20)	$6.53
Valuation	**$30.00**

OUTLOOK

ContraFect Corp. (CFRX) is continuing to enroll patients into the Phase 3 DISRUPT trial, which is evaluating exebacase for the treatment of patients with bacteremia caused by *Staphylococcus aureus*. The trial is anticipated to enroll approximately 350 patients randomized 2:1 to receive exebacase or placebo in addition to standard of care antibiotics for bacteremia caused by *S. aureus*, including methicillin-resistant *S. aureus* (MRSA) bacteremia, including right-sided endocarditis. An interim futility analysis will be performed once the first 60% of patients enrolled into the trial are evaluable for efficacy.

SUMMARY DATA

52-Week High	**$12.30**
52-Week Low	**$2.90**
One-Year Return (%)	**47.07**
Beta	**0.60**
Average Daily Volume (sh)	**201,398**
Shares Outstanding (mil)	**15**
Market Capitalization ($mil)	**$100**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**N/A**
Insider Ownership (%)	**3**
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	**-2.6**
P/E using 2020 Estimate	**-2.7**

Risk Level	**High**
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 E	0 E	0 E	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	-$0.45 E	-$0.47 E	-$0.48 E	-$0.39 E	-$1.77 E
2021					-$1.31 E
2022					-$1.21 E

WHAT'S NEW

Business Update

Update on Phase 3 DISRUPT Trial

In January, 2020, ContraFect Corp. (CFRX) announced the first patient had been dosed in the Phase 3 DISRUPT (Direct Lysis of *Staph aureus* Resistant Pathogen Trial) study of exebacase in patients with *Staphylococcus aureus* bacteremia, including right-sided endocarditis (NCT04160468). The randomized, double blind, placebo controlled trial is being conducted at 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 primary endpoint of the trial will be 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. An interim futility analysis will be conducted after the first 60% of patients enrolled into the trial are evaluable for efficacy.

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.

Breakthrough Therapy Designation for Exebacase

On Feb. 24, 2020, ContraFect announced that the US FDA has granted Breakthrough Therapy designation to exebacase for the treatment of MRSA bacteremia, including right-sided endocarditis, when used in conjunction with standard of care antibiotics. The FDA established the Breakthrough Therapy program to speed the development of medicines for serious or life-threatening diseases with preliminary clinical evidence that may show the investigational product could substantially improve at least one clinically significant endpoint over currently available therapies.

Breakthrough Therapy designation was granted to exebacase based on data from the Phase 2 clinical trial showing treatment with exebacase led to a 42.8 percent higher responder rate at Day 14 in patients with MRSA infections compared to treatment with standard of care antibiotics alone (74.1% vs. 31.3%; *P*=0.01). Exebacase carries both Breakthrough Therapy and Fast Track designation, which will allow for a rolling BLA submission and priority review.

Compassionate Use of Exebacase in France

In January 2020, ContraFect announced that four patients with post-operative prosthetic joint infections (PJIs) have been treated with exebacase under Temporary Authorizations for Use from the French National Agency for Medicines and Health Products Safety in collaboration with Dr. Tristan Ferry at the Hôpital de la Croix Rousse in Lyon, France.

The patients that have been treated thus far had longstanding, treatment refractory PJIs. Following treatment, the promising signals seen in these patients has led to the temporary authorization to use exebacase being extended to patients with *Staphylococcal* PJI that occurs shortly after surgery to hopefully avoid significant damage to the joint.

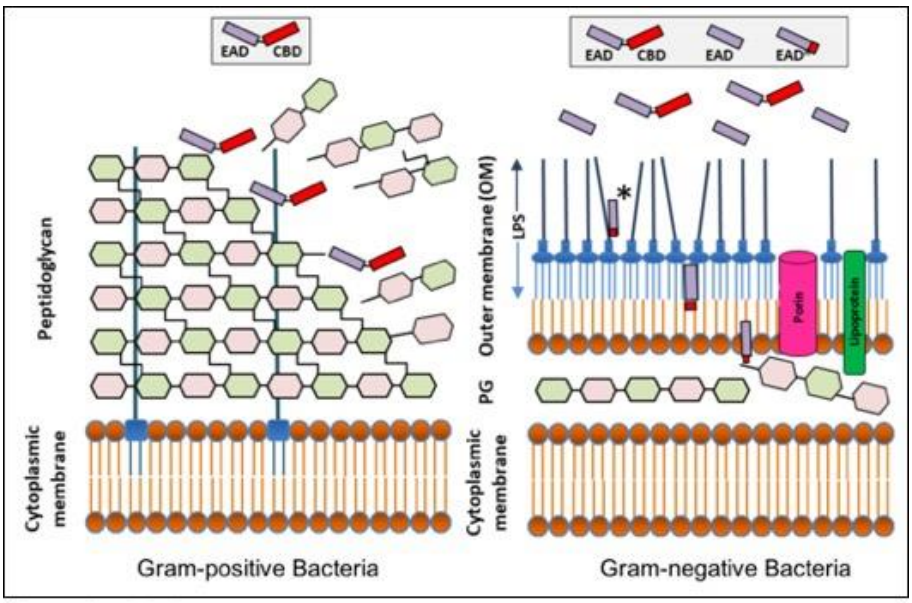
Biofilm formation in prosthetic joints is a very challenging infection to clear with traditional antibiotics, which typically leads to additional surgery and possibly replacement of the joint to ultimately get rid of the infection. The company has previously shown exebacase is able to rapidly clear biofilms, as shown in the following figures, thus we view the application of the drug in treating difficult-to-clear prosthetic infections as a natural next step in its development life cycle.

Source: ContraFect Corp.

First Gram-Negative Lysin Candidate Announced

In December 2019, ContraFect announced it has selected its next development product candidate, CF-370, which is an engineered lysin targeting *Pseudomonas aeruginosa*, a Gram-negative bacterial species that is listed as a serious threat in the Centers for Disease Control and Prevention (CDC) 2019 Antibiotic Resistance Threats Report. Gram-negative bacteria are responsible for a number of different bacterial infections and the emergence of antibiotic resistant strains is leading to a potential public health crisis. Lysins represent a novel means to treat these infections through their ability to cleave peptidoglycan bonds (peptidoglycan is the main structural component of bacterial cell walls), however their use against Gram-negative pathogens has been hindered by their inability to penetrate the outer membrane.

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 a preclinical rabbit pneumonia model, a single dose of CF-370 either alone or in combination with meropenem resulted in increased survival and reductions in bacterial counts in lung, kidney, and spleen. The company will be presenting this and other detailed preclinical data supporting the advancement of CF-370 at an upcoming scientific conference.

Financial Update

On March 19, 2020, ContraFect announced financial results for the fourth quarter and full year 2019. As expected, the company did not report any revenues for the quarter or the full year. Net loss for the fourth quarter of 2019 was $10.4 million, or $1.11 per share, compared to net income of $5.9 million, or income of $0.75 per share, for 2018. The change to a net loss was due to an $18.5 million increase in the non-cash charge for the change in fair value of warrant liabilities. R&D expenses for the fourth quarter of 2019 were $3.9 million compared to $6.7 million for the fourth quarter of 2018. The decrease was primarily due to a reduction in clinical trial spending. G&A expenses for the fourth quarter of 2019 were $2.6 million compared to $2.1 million for the fourth quarter of 2018. The increase was due to an increase in legal fees and expansion of the company's intellectual property portfolio.

For the full year 2019, net loss was $12.8 million, or $1.54 per share, compared to a net loss of $37.7 million, or $4.95 per share, for 2018. The decrease was primarily due to a $21.9 million decrease in the non-cash charge for the change in fair value of warrant liabilities. R&D expenses for 2019 were $18.1 million compared to $22.4 million for 2018. The decrease was primarily due to a reduction in clinical trial expenses. G&A expenses in 2019 were $9.8 million compared to $8.7 million in 2018. The increase was primarily due to increased legal fees, consulting fees, and personnel expenses.

As of Dec. 31, 2019, ContraFect had approximately $24.2 million in cash and cash equivalents, which we estimate will be sufficient to fund operations into the third quarter of 2020. As of Mar. 9, 2020, ContraFect had approximately 15.3 million shares of common stock and when factoring in stock options and warrants a fully diluted share count of approximately 19.6 million.

Conclusion

The next major milestone for the DISRUPT trial will be when enrollment reaches 60%, which will trigger the interim futility analysis. We believe the company may be in a position to offer guidance about when that analysis may take place once the rate of enrollment is known for a few months in addition to what impact, if any, the coronavirus pandemic will have on enrollment. Our current valuation is $30 per share.

PROJECTED FINANCIALS

ContraFect Corp.	2019 A	Q1 E	Q2 E	Q3 E	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	$4.5	$4.7	$4.8	$5.0	$19.0	$21.0	$23.0
General & Administrative	$9.8	$2.4	$2.5	$2.6	$2.7	$10.2	$10.5	$11.0
Other Expenses	$0	$0	$0	$0	$0	$0	$0	$0
Operating Income	($27.9)	($6.9)	($7.2)	($7.4)	($7.7)	($29.2)	($31.5)	($34.0)
Operating Margin		-	-	-	-			
Non-Operating Expenses (Net)	$15.1	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	($12.8)	($6.9)	($7.2)	($7.4)	($7.7)	($29.2)	($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)**	**($6.9)**	**($7.2)**	**($7.4)**	**($7.7)**	**($29.2)**	**($31.5)**	**($34.0)**
Net Margin		-	-	-	-			
Reported EPS	**($1.54)**	**($0.45)**	**($0.47)**	**($0.48)**	**($0.50)**	**($1.90)**	**($1.43)**	**($1.36)**
YOY Growth		-	-	-	-			
Basic Shares Outstanding	8.3	15.3	15.3	15.4	15.4	15.4	22.0	25.0

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

HISTORICAL STOCK PRICE

Source: Zacks Investment Research

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 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.