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ContraFect Corp. (CFRX-NASDAQ)

CFRX: Planning for Phase 3 Trial of Exebacase in S. Aureus *Bacteremia…*

Based on our probability adjusted DCF model that takes into account potential future revenues from CF-301 in bacteremia and CF-404 in influenza, CFRX is valued at $4/share. This model is highly dependent upon continued clinical success of CF-301 and CF-404 and will be adjusted accordingly based upon future clinical results.

Current Price (03/20/19)	$0.36
Valuation	**$4.00**

OUTLOOK

On March 14, 2019, ContraFect Corp. (CFRX) announced financial results for the fourth quarter and full year 2018 and provided a business update. The company will soon be receiving the full data set for the Phase 2 clinical trial of exebacase (CF-301) in patients with bacteremia caused by *Staphylococcus aureus*. ContraFect had previously announced positive topline data that showed a clinically meaningful 10.4% improvement in the responder rate at day 14 and a 42.8% increase in responder rate at day 14 in a pre-specified analysis of methicillin-resistant *S. aureus* (MRSA) infected patients. Following receipt of the full data package, the company will conduct an "end-of-Phase 2" meeting with the FDA to receive regulatory guidance on a Phase 3 program for exebacase. We anticipate that meeting taking place in mid-2019 with the potential for a Phase 3 trial to initiate in the first half of 2020.

SUMMARY DATA

52-Week High	**$2.82**
52-Week Low	**$0.36**
One-Year Return (%)	**-81.44**
Beta	**-0.49**
Average Daily Volume (sh)	**465,371**
Shares Outstanding (mil)	**79**
Market Capitalization ($mil)	**$29**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**56**
Insider Ownership (%)	**7**
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 2018 Estimate	**-4.6**
P/E using 2019 Estimate	**-4.0**

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)
2018	0 A	0 A	0 A	0 A	0 A
2019	0 E	0 E	0 E	0 E	0 E
2020					0 E
2021					0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2018	-$0.26 A	-$0.27 A	-$0.06 A	$0.07 A	-$0.50 A
2019	-$0.09 A	-$0.09 A	-$0.08 A	-$0.08 E	-$0.34 E
2020					-$0.36 E
2021					-$0.39 E

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Business Update

Awaiting Final Data Set for Phase 2 Trial

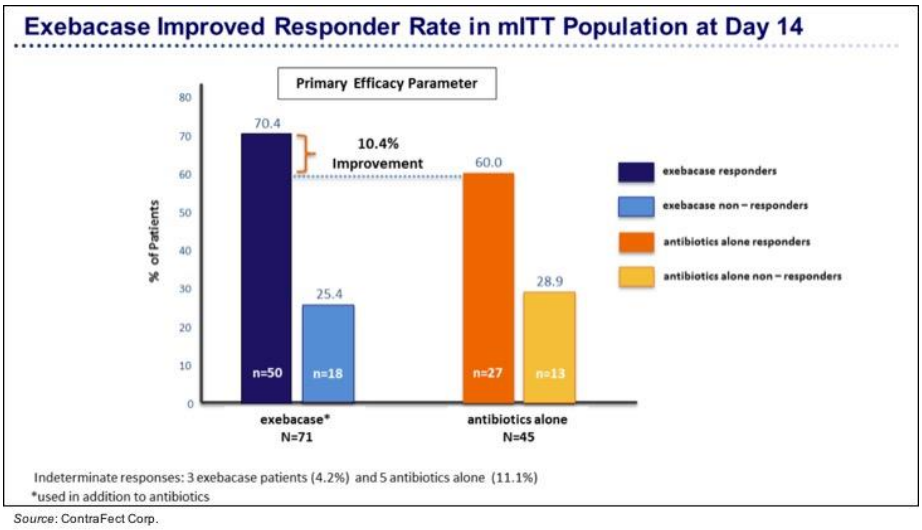
ContraFect Corp. (CFRX) is developing exebacase (CF-301), the company's lead lysin product, for the treatment of bacteremia caused by *Staphylococcus aureus* infections. Lysins are naturally occurring anti-bacterial hydrolytic enzymes that are produced by bacteriophages, which are virus' that infect and kill bacteria. Exebacase has been tested in a number of pre-clinical studies and the company recently announced positive topline results from a Phase 2 study of exebacase (discussed below). We estimate that the final patient recently completed the 180-day follow-up appointment and that the company will be receiving the final data set for the trial in the second quarter of 2019. Following receipt of the data set, the company will conduct an 'end-of-Phase 2' meeting with the FDA to receive regulatory guidance on a Phase 3 clinical trial, followed by a meeting with the EMA in the second half of 2019. We anticipate learning additional details about the Phase 3 trial in the second half of 2019 following the company's meeting with regulatory authorities, and anticipate a Phase 3 study initiating in the first half of 2020.

Review of Phase 2 Topline Data

In January 2019, ContraFect announced topline results from the Phase 2 trial of exebacase in patients with bacteremia caused by *S. aureus*, including those with endocarditis. This was an international, multicenter, randomized, double blind, placebo controlled trial with a superiority comparison between exebacase or placebo combined with the standard of care antibiotics. A total of 121 patients were randomized 3:2 to receive a single dose of 0.25 mg/kg exebacase or placebo administered via a two-hour infusion along with the standard of care antibiotics. The primary endpoint of the study was early clinical response. A patient was considered a responder if they were alive, had an improvement or resolution of the signs and symptoms attributable to the *S. aureus* infection, there were no additional medical interventions required, and there was no evidence of a spread of the infection.

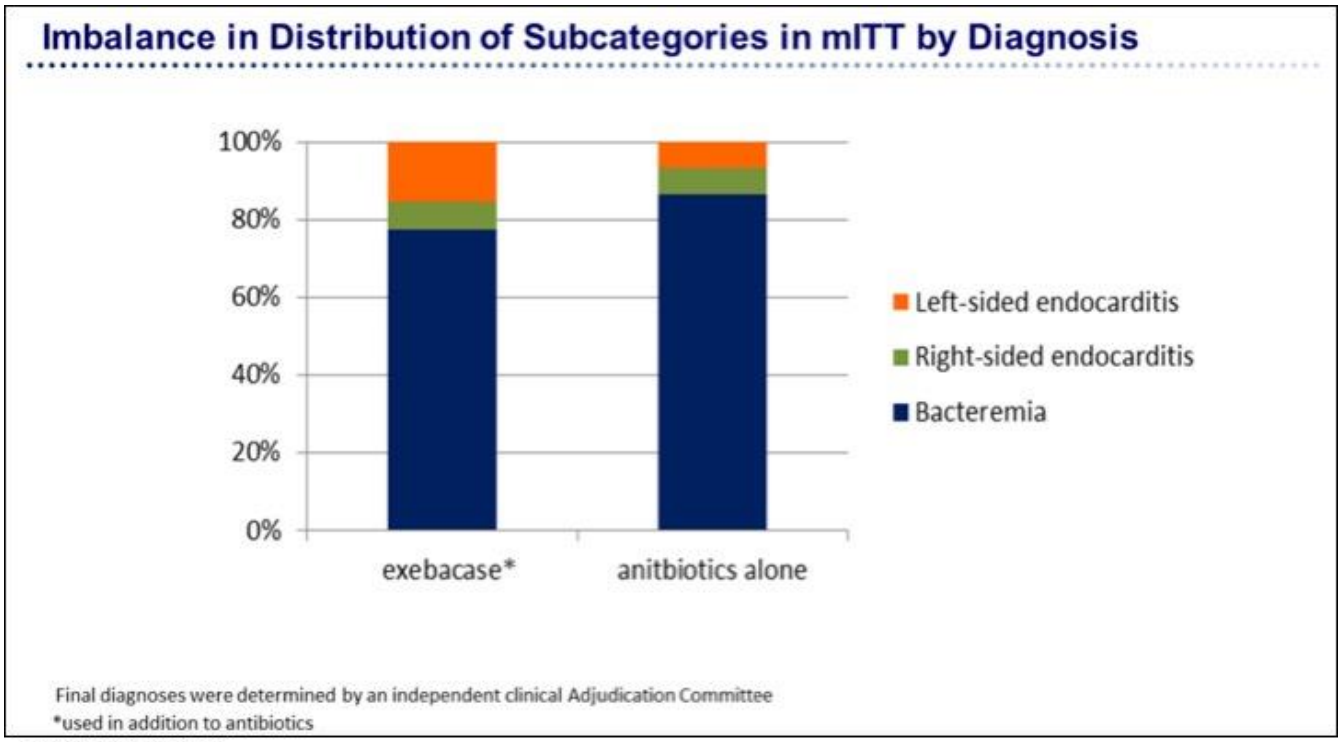
There were 116 patients in the modified intent-to-treat (mITT) population that each had confirmed *S. aureus* bacteremia with or without endocarditis. The majority of subjects were enrolled in the U.S. (79%), but sites in Latin America, the E.U., Russia, and Israel also enrolled patients. The average age of study subjects was 56 and 67.8% of the population was male Caucasians. The standard of care antibiotics were vancomycin or daptomycin for methicillin-resistant *S. aureus* (MRSA) or semi-synthetic penicillins or first-generation cephalosporins for methicillin-sensitive S. aureus (MSSA).

The following figure shows the topline results for the primary endpoint of the study, which was responder analysis at Day 14. Treatment with exebacase in addition to standard of care antibiotics resulted in a 10.4% improvement compared to treatment with only antibiotics (*P*=0.314). In planning for the study, the company had been assuming that the patients receiving only standard of care antibiotics would have an approximately 60% responder rate, so that came in just as expected.



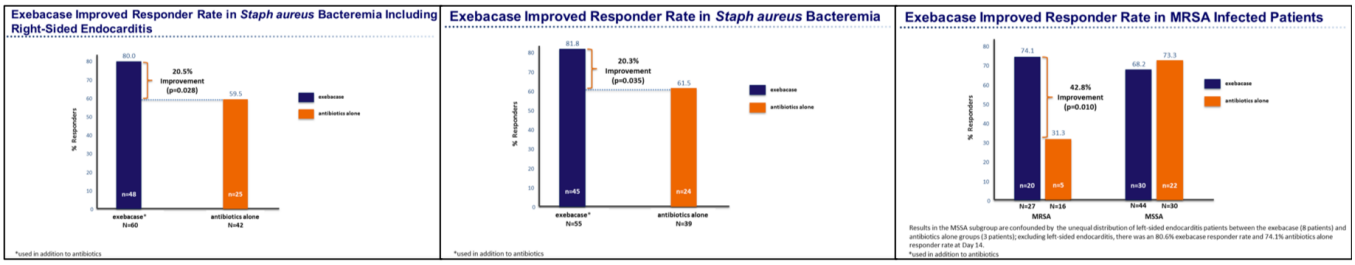
Source: ContraFect Corp.

While disappointing that the study did not show a statistically significant difference for the primary endpoint, it is encouraging that the use of exebacase improved patient outcomes. One possible reason for why the results in the exebacase-treated group were not better is the disparity in the number of patients with left-sided endocarditis, a notoriously difficult condition to treat (Cahill *et al*., 2017). As the following graph shows, there was a larger percentage of patients with left-sided endocarditis in the exebacase treated group (15.5%) compared to the antibiotics alone group (6.7%). As an example of how difficult patients with left-sided endocarditis are to treat, in a clinical trial comparing the efficacy of daptomycin to vancomycin for the treatment of bacteremia and endocarditis caused by *S. aureus* only 11% (1/9) of patients with left-sided endocarditis responded to treatment with daptomycin (Fowler *et al*., 2006).



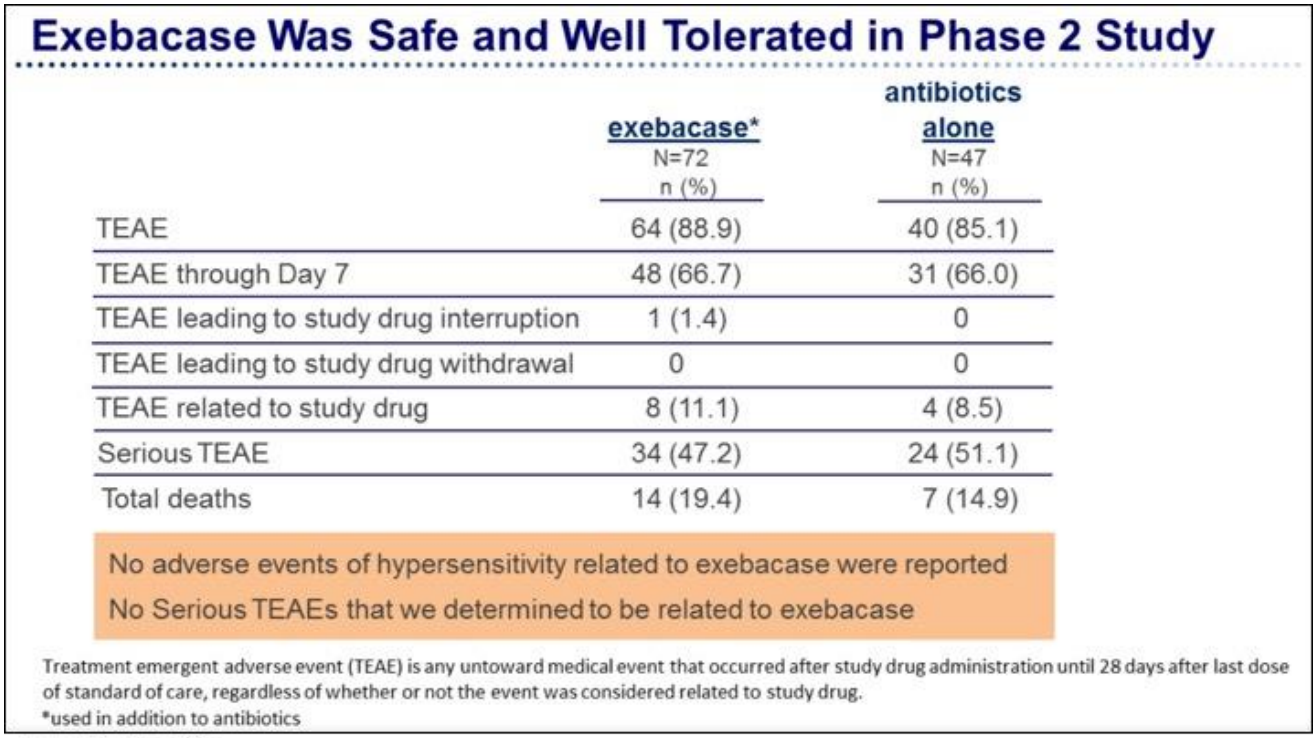
Source: ContraFect Corp.

There were a number of important pre-specified subgroup analyses in which higher response rates were seen in patients treated with exebacase. The following charts show that treatment with exebacase resulted in higher responder rates at Day 14 for those with *S. aureus* bacteremia and right-sided endocarditis (*P*=0.028), *S. aureus* bacteremia only (*P*=0.035), and in those with MRSA (*P*=0.01). Once again, the MSSA results were confounded by the unequal distribution of left-sided endocarditis patients. If those patients were excluded, treatment with exebacase resulted in a numerically higher response rate.



Source: ContraFect Corp.

Lastly, exebacase was safe and very well tolerated. The following chart shows that the percentage of treatment-emergent adverse events (TEAE) was similar in both treatment groups and there were no reports of adverse events due to hypersensitivity to exebacase along with no serious TEAEs that were determined to be related to exebacase. The company will test for the presence of anti-drug antibodies (ADAs) after the six-month follow-up.



Source: ContraFect Corp.

Non-Dilutive Funding from CARB-X

In January 2019, ContraFect announced that the Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator (CARB-X) awarded the company $2.3 million in research funding to be awarded over the next two years. The grant will be used to fund additional development of a lysin targeted to the Gram-negative pathogen *Pseudomonas aeruginosa*. The company had previously received a $2.1 million grant from CARB-X in 2017.

In March 2019, ContraFect announced that CARB-X awarded the company up to $6.94 million in funding research to advance development of the newly discovered class of amurin peptides as potential therapies for serious and life-threatening infections caused by Gram-negative pathogens. Amurins are peptides produced by certain bacteriophage that exhibit broad spectrum anti-microbial activity against a wide range of Gram-negative pathogens. They also exhibit synergistic activity with standard-of-care antibiotics and have the ability to eliminate biofilms.

CARB-X is a global partnership established to accelerate early stage development of novel antimicrobials to help address the problem of antibiotic resistance. Funding for CARB-X is provided by the Biomedical Advanced Research and Development Authority (BARDA), the Wellcome Trust, the Bill and Melinda Gates Foundation, and the NIH.

Financial Update

On March 14, 2019, ContraFect announced financial results for the fourth quarter and full year 2018. As expected, the company did not report any revenues for the quarter or full year. Net income for the fourth quarter of 2018 was $5.9 million, or $0.07 per share, compared to a net loss of $4.8 million, or $0.06 per share, in the fourth quarter of 2017. The change in per share earnings was due to an increase of $12.1 million, or $0.15 per share, in the non-cash gain for the change in fair value of warrant liabilities. R&D expenses in the fourth quarter of 2018 were $6.7 million compared to $4.4 million in the fourth quarter of 2017. The increase was primarily attributable to increased expenses for the Phase 2 clinical trial. G&A expenses were $2.1 million in the fourth quarter of 2018 compared to $3.0 million in the fourth quarter of 2017. The decrease was mostly due to a decrease in administrative personnel and severance-related costs.

For 2018, the company reported a net loss of $37.7 million, or $0.50 per share, compared to a net loss of $15.5 million, or $0.28 per share, in 2017. The change in net loss includes an increase of $18.8 million in

the non-cash gain for the change in fair value of warrant liabilities. R&D expenses in 2018 were $22.4 million compared to $17.3 million in 2017. The increase in R&D expenses was primarily attributable to the increase in expenditures related to the Phase 2 clinical trial and an overall increase in laboratory and external research costs. G&A expenses in 2018 were $8.7 million compared to $9.2 million in 2017. The decrease in G&A expenses was due to lower severance costs.

As of Dec. 31, 2018, ContraFect had cash, cash equivalents, and marketable securities of approximately $30.5 million, which we believe is sufficient to fund operations through the end of 2019. As of Mar. 7, 2019, the company had approximately 79.4 million shares outstanding, and when factoring in stock options and warrants the fully diluted share count stands at approximately 117.8 million.

Conclusion

Following release of the Phase 2 results the stock dropped by over 50% and has continued to trend downward, however we don't believe that the results warranted that type of reaction in the stock. This was a proof-of-concept, first-in-patient study of exebacase (no other lysin has been tested in patients prior to this), thus we believe that the main objective of this study was to identify the proper patient population to target in a Phase 3 program. By this metric, we believe the trial was successful as the company has identified *S. aureus* bacteremia patients with right-sided endocarditis (patients with left-sided endocarditis will be excluded) as the population most likely to benefit from treatment with exebacase. In addition, we believe the Phase 2 results have validated the lysin platform. Our valuation remains at $4.

PROJECTED FINANCIALS

ContraFect Corp.	2018 A	Q1 E	Q2 E	Q3 E	Q4 E	2019 E	2020 E	2021 E
CF-301 (Bacteremia)	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth		-	-	-	-			
CF-404 (Flu)	$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	$22.4	$4.7	$5.0	$5.2	$5.3	$20.2	$24.0	$28.0
General & Administrative	$8.7	$2.2	$2.2	$2.3	$2.3	$9.1	$9.5	$10.0
Other Expenses	$0	$0	$0	$0	$0	$0	$0	$0
Operating Income	($31.1)	($7.0)	($7.2)	($7.5)	($7.6)	($29.3)	($33.5)	($38.0)
Operating Margin		-	-	-	-			
Non-Operating Expenses (Net)	($6.6)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	($37.7)	($7.0)	($7.2)	($7.5)	($7.6)	($29.3)	($33.5)	($38.0)
Income Taxes Paid	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	**($37.7)**	**($7.0)**	**($7.2)**	**($7.5)**	**($7.6)**	**($29.3)**	**($33.5)**	**($38.0)**
Net Margin		-	-	-	-			
Reported EPS	**($0.50)**	**($0.09)**	**($0.09)**	**($0.08)**	**($0.08)**	**($0.34)**	**($0.36)**	**($0.39)**
YOY Growth		-	-	-	-			
Basic Shares Outstanding	76.1	79.5	80.0	90.0	91.0	85.1	92.0	98.0

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

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