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ContraFect Corp. (CFRX-NASDAQ)

CFRX: Exebacase Improves Clinical Outcomes in Phase 2 Trial…

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 (01/09/19)	$0.68
Valuation	**$4.00**

OUTLOOK

On January 7, 2019, ContraFect Corp. (CFRX) announced topline results from the Phase 2 trial of exebacase (CF-301) in patients with bacteremia caused by *Staphylococcus aureus*, including those with endocarditis. Treatment with exebacase in addition to standard of care antibiotics resulted in a clinically meaningful increase in the primary endpoint of clinical response at Day 14 along with higher response rates in a number of pre-specified subgroups, including in patients with methicillin-resistant *S. aureus* (MRSA) infections (*P*=0.01) and in patients with only *S. aureus* bacteremia (*P*=0.035). We view the trial as a success as it identified *S. aureus* bacteremia patients with or without right-sided endocarditis as the patient population most likely to benefit from treatment with exebacase. In addition, we believe this trial validated the lysin technology, and we anticipate the company advancing exebacase into a Phase 3 program with additional lysin development products moving into the clinic.

SUMMARY DATA

52-Week High	**$2.82**
52-Week Low	**$0.68**
One-Year Return (%)	**-42.60**
Beta	**0.37**
Average Daily Volume (sh)	**586,118**
Shares Outstanding (mil)	**79**
Market Capitalization ($mil)	**$54**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**57**
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)
2017	0 A	0 A	0 A	0 A	0 A
2018	0 A	0 A	0 A	0 E	0 E
2019					0 E
2020					0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2017	-$0.15 A	-$0.07 A	-$0.02 A	-$0.06 A	-$0.28 A
2018	-$0.26 A	-$0.27 A	-$0.06 A	-$0.09 E	-$0.67 E
2019					-$0.36 E
2020					-$0.37 E

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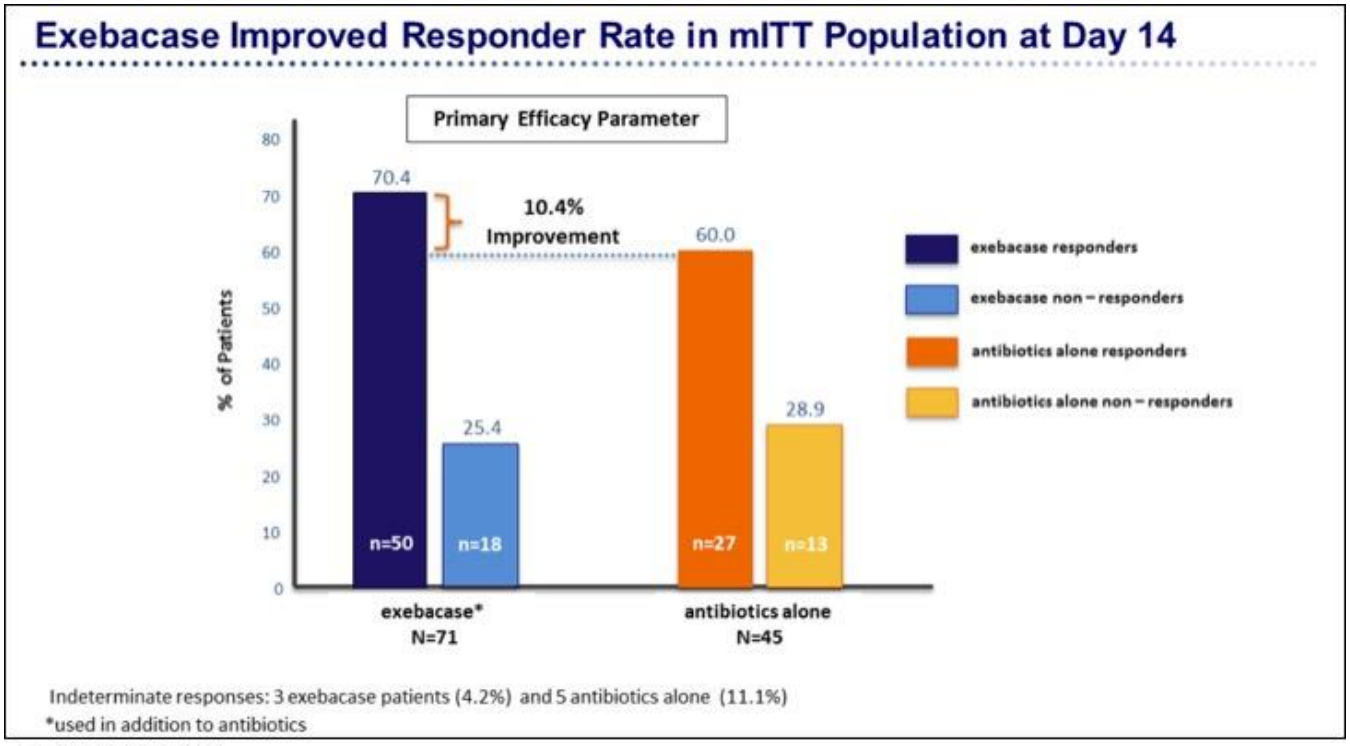
Business Update

Treatment with Exebacase Beneficial to S. Aureus *Bacteremia Patients*

On January 7, 2019, ContraFect Corp. (CFRX) announced topline results from the Phase 2 trial of exebacase (CF-301) in patients with bacteremia caused by *Staphylococcus 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).

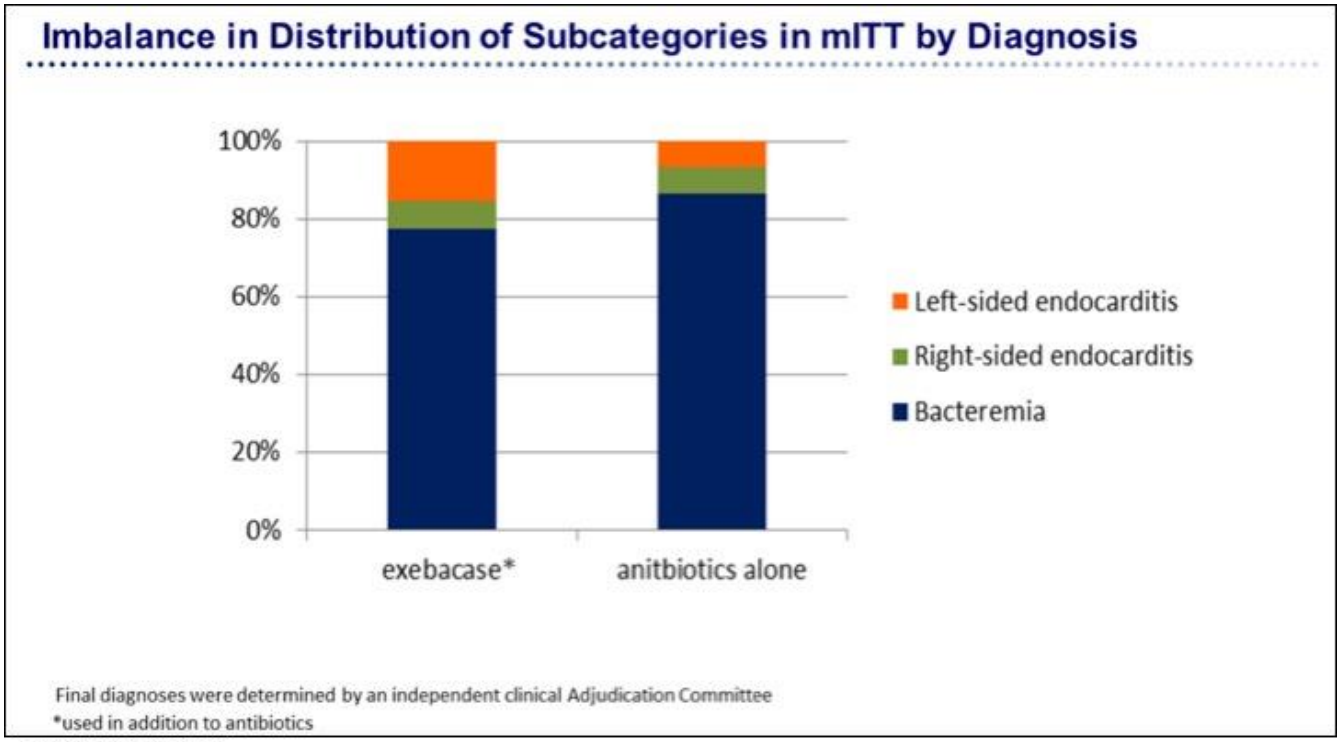
The following figure shows the topline results for the primary endpoint of the study, which was responder analysis at Day 14. Treatment with exebacase in addition to standard of care antibiotics resulted in a 10.4% improvement compared to treatment with only antibiotics (*P*=0.314). In planning for the 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.

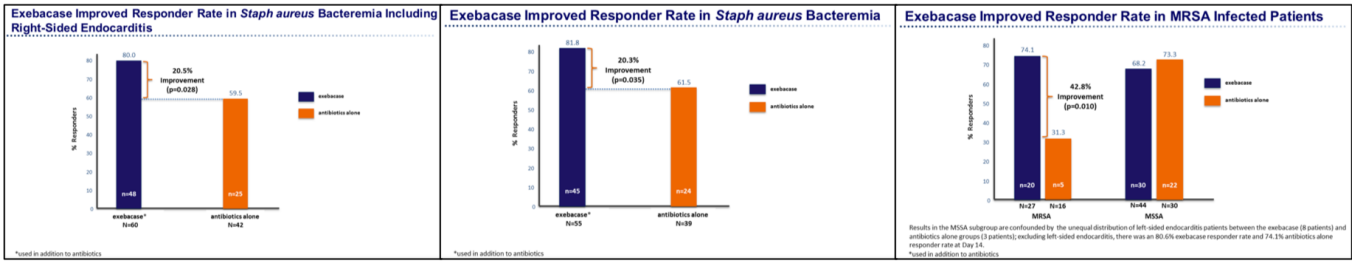
While disappointing that the study did not show a statistically significant difference for the primary endpoint, it is encouraging that the use of exebacase improved patient outcomes. One possible reason for why the results in the exebacase-treated group were not better is the disparity in the number 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.

Exebacase Was Safe and Well Tolerated in Phase 2 Study

	exebacase* N=72 n (%)	antibiotics alone N=47 n (%)
TEAE	64 (88.9)	40 (85.1)
TEAE through Day 7	48 (66.7)	31 (66.0)
TEAE leading to study drug interruption	1 (1.4)	0
TEAE leading to study drug withdrawal	0	0
TEAE related to study drug	8 (11.1)	4 (8.5)
Serious TEAE	34 (47.2)	24 (51.1)
Total deaths	14 (19.4)	7 (14.9)

No adverse events of hypersensitivity related to exebacase were reported

No Serious TEAEs that we determined to be related to exebacase

Treatment emergent adverse event (TEAE) is any untoward medical event that occurred after study drug administration until 28 days after last dose of standard of care, regardless of whether or not the event was considered related to study drug.

*used in addition to antibiotics

Source: ContraFect Corp.

The next step for ContraFect will be to meet with the FDA and EMA to formulate a Phase 3 development plan, which we anticipate taking place in the second half of 2019. Assuming that an agreement on a trial design can be met relatively quickly, we anticipate that a Phase 3 trial could initiate in the first half of 2020.

Conclusion

Investors were disappointed that the trial did not hit statistical significance for the primary endpoint (as evidenced by the fact that the stock was down over 50% following release of the results), however we think this may be a bit short-sighted. 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. Unfortunately, due to the drop in stock price the company will now have to raise funds for the Phase 3 program at depressed prices, and due to this our valuation has been reduced to $4. We ultimately believe that this study has validated the lysin technology, and we look forward to the company advancing exebacase to Phase 3 while also putting additional lysin development products into the clinic.

PROJECTED FINANCIALS

ContraFect Corp.	2017 A	Q1 A	Q2 A	Q3 A	Q4 E	2018 E	2019 E	2020 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	$17.3	$4.7	$5.3	$5.7	$4.9	$20.6	$19.5	$20.0
General & Administrative	$9.2	$2.2	$2.2	$2.1	$2.4	$9.0	$10.0	$10.5
Other Expenses	$0	$0	$0	$0	$0	$0	$0	$0
Operating Income	($26.6)	($7.0)	($7.5)	($7.8)	($7.3)	($29.6)	($29.5)	($30.5)
Operating Margin		-	-	-	-			
Non-Operating Expenses (Net)	$11.0	($12.1)	($12.6)	$3.4	$0.0	($21.3)	($0.4)	($0.4)
Pre-Tax Income	($15.5)	($19.1)	($20.1)	($4.4)	($7.3)	($50.9)	($29.9)	($30.9)
Income Taxes Paid	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	**($15.5)**	**($19.1)**	**($20.1)**	**($4.4)**	**($7.3)**	**($50.9)**	**($29.9)**	**($30.9)**
Net Margin		-	-	-	-			
Reported EPS	**($0.28)**	**($0.26)**	**($0.27)**	**($0.06)**	**($0.09)**	**($0.67)**	**($0.36)**	**($0.37)**
YOY Growth		-	-	-	-			
Basic Shares Outstanding	55.6	73.7	73.7	77.4	79.5	76.1	82.0	84.0

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

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