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ContraFect Corp. (CFRX-NASDAQ)

CFRX: Planning to Initiate Phase 3 Superiority Trial for Exebacase in 4Q19…

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 $4/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 (10/07/19)	$0.38
Valuation	**$4.00**

OUTLOOK

On October 2, 2019, ContraFect Corp. (CFRX) announced plans for a Phase 3 superiority trial for exebacase in patients with bacteremia caused by *Staphylococcus aureus*. Following a successful 'end-of-Phase 2' meeting with the FDA, the company is planning to conduct a single Phase 3 trial with a primary endpoint of clinical response at Day 14 in patients with methicillin-resistant *S. aureus* (MRSA) bacteremia, including right-sided endocarditis. A total of 350 patients will be randomized 2:1 to receive either exebacase or placebo, with all patients receiving standard of care antibiotics. In the Phase 2 study, results showed a 43% higher responder rate at Day 14 among exebacase-treated MRSA bacteremia patients compared to those treated with only standard of care antibiotics, the same endpoint as will be employed in the Phase 3 trial.

SUMMARY DATA

52-Week High	**$2.47**
52-Week Low	**$0.31**
One-Year Return (%)	**-80.76**
Beta	**0.15**
Average Daily Volume (sh)	**246,131**
Shares Outstanding (mil)	**79**
Market Capitalization ($mil)	**$30**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**35**
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	**-2.8**
P/E using 2019 Estimate	**-0.9**

Risk Level	**High**
Type of Stock	**Small-Blend**
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 A	0 A	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	$0.15 A	-$0.11 A	-$0.08 E	-$0.08 E	-$0.14 E
2020					-$0.36 E
2021					-$0.39 E

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WHAT'S NEW

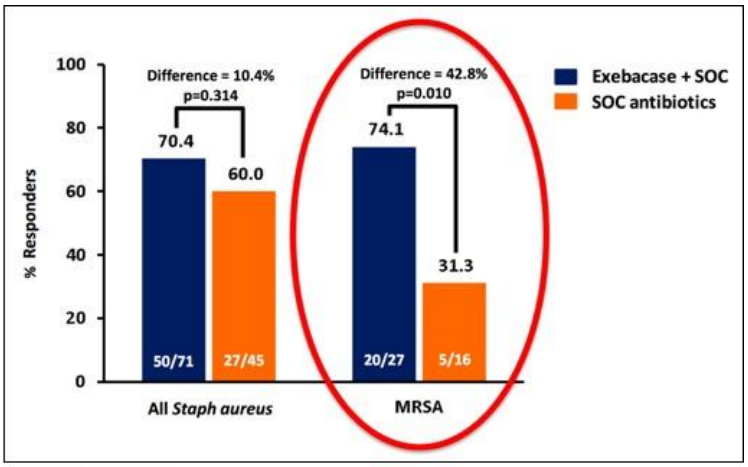
Business Update

Phase 3 Clinical Trial to Initiate in 4Q19

On October 2, 2019, ContraFect Corp. (CFRX) announced that following a successful 'end-of-Phase 2' meeting with the FDA the company is planning to conduct a single Phase 3 clinical trial of exebacase in patients with *Staphylococcus aureus* bacteremia, including right-sided endocarditis. The randomized, double blind, placebo controlled study will be 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. 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. An interim futility analysis will be conducted following enrollment of approximately 60% of patients. We anticipate the trial initiating in the fourth quarter of 2019.

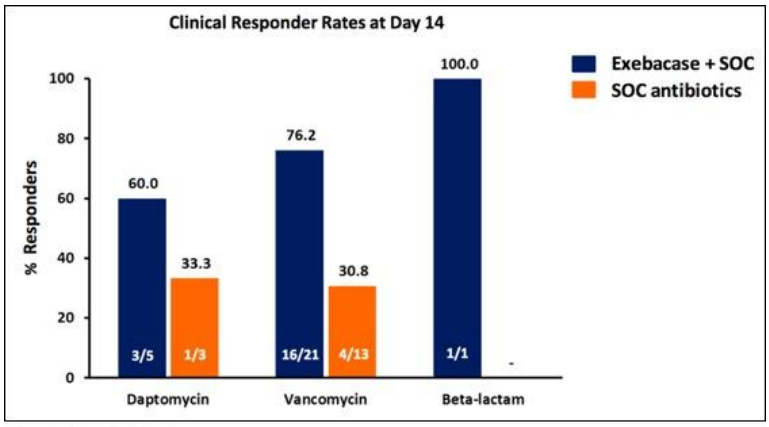
Phase 2 Data Supports Phase 3 Plan

ContraFect had previously reported data from the company's Phase 2 clinical trial of exebacase in patients with *S. aureus* bacteremia. While the trial did not meet the primary endpoint of clinical response at Day 14 in all *S. aureus* patients, results showed a 42.8% higher responder rate at Day 14 in a prespecified MRSA subgroup.



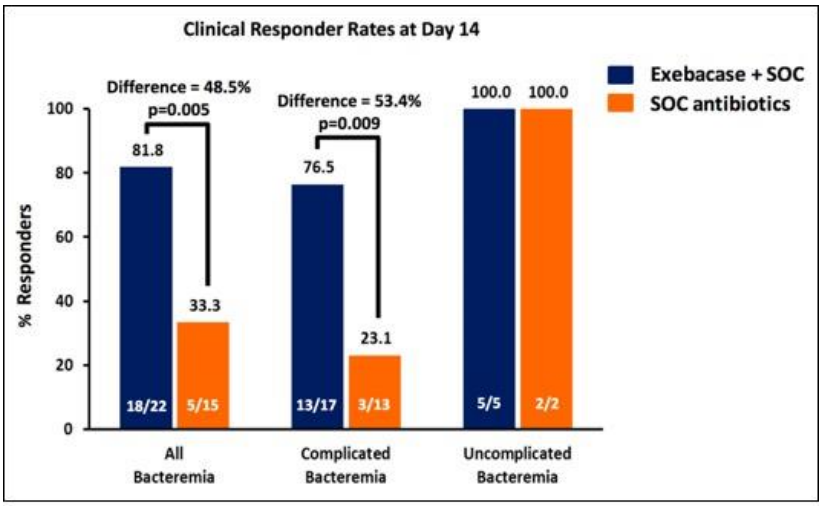
Source: ContraFect Corp.

When examining MRSA patients stratified by the antibiotic used in treatment, exebacase showed consistently higher response rates regardless of the standard of care treatment, which for MRSA infection is typically either daptomycin or vancomycin.



Source: ContraFect Corp.

Lastly, treatment with exebacase was also associated with higher response rates when examining MRSA patients who had bacteremia as well as complicated bacteremia, in which exebacase treatment resulted in a 53.4% higher responder rate at Day 14.



Source: ContraFect Corp.

Some of the more intriguing data to come from the Phase 2 trial had to do with health economic data, which showed that the length of hospital stay was reduced for MRSA patients following study drug administration (6.0 days for exebacase-treated vs. 10.0 days for standard of care alone) as well as the all-cause 30-day hospital readmission rates (16.0% vs. 30.8% in the exebacase vs. standard of care groups) and the *S. aureus* 30-day hospital readmission rates (8.0% vs 15.4% in the exebacase vs. standard of care groups). These types of numbers should help facilitate reimbursement talks with payers.

In summary, treatment with exebacase and standard of care antibiotics resulted in superior clinical responder rates at Day 14 compared to standard of care antibiotics alone as well as a reduction in the length of hospitalization and 30-day readmission rates in MRSA patients.

Amurin Peptide Eliminates Biofilm Caused by Gram Negative Pathogen

On September 4, 2019, ContraFect announced a poster presentation at the American Society of Microbiology and European Society of Clinical Microbiology and Infectious Disease (ASM/ESCMID) Conference on Drug Development to Meet the Challenge of Antimicrobial Resistance that reported results from an *ex vivo* study of the company's amurin peptide, App2-M1, in treating catheter biofilms taken from patients with suspected catheter-related bloodstream infections. Amurins are peptides produced by certain bacteriophage that exhibit broad spectrum anti-microbial activity against a wide range of Gram-negative pathogens.

Three infected hemodialysis catheters were removed from two patients (Patient 1 = Catheter A; Patient 2 = Catheters B and C), segmented, and separated into different treatment groups with App2-M1 (1 and 10 μg/mL), 1 μg/mL meropenem (a broad-spectrum antibiotic used against Gram-positive and Gram-negative pathogens), or buffer control. Each of the catheters was shown to have adherent mucoid biofilms within the lumen. The following table shows that treatment of catheter A with 10 μg/mL App2-M1 resulted in complete elimination of the biofilm. Bacterial colonies were enumerated following a 24 hour incubation at 37ºC with the limit of detection being 0.7 Log_{10} CFU/g catheter.

Study groups[a]	App2-M1[a] (μg/mL)	Log_{10} CFU/g[b]
Treatment control	0	3.37
App2-M1 alone	10	<0.7

Source: Oh *et al.*, 2019

Similar results were seen with treatment of Catheter's B and C with only 1 μg/mL App2-M1. Interestingly, meropenem treatment up to 100 μg/mL did not eradicate the biofilm.

Study groups[a]	Catheter B	Catheter C
	Log_{10} CFU/g[c]	Log_{10} CFU/g[d]
Treatment control	4.24	4.22
App2-M1 (1 μg/mL)	<0.7	<0.7
Meropenem (1,10,100 μg/mL)	n.d.	3.16

Source: Oh *et al.*, 2019

16S rRNA sequencing identified the presence of *Stenotrophomonas* species on each catheter, with *S. maltophilia* confirmed on all three. Colonies recovered from each catheter were used to determine the minimum inhibitory concentration (MIC). The following table shows that similar MIC values were obtained for the organisms obtained from each catheter and that *S. maltophilia* was resistant to meropenem but sensitive to App2-M1.

		MIC (μg/mL)[a]	
Catheter	Organism	App2-M1	Meropenem
A	*S. maltophilia*	2	>32
B	*S. maltophilia*	1	>32
C	*S. maltophilia*	1	>32

Source: Oh *et al.*, 2019

The conclusion from this study is that the amurin peptide App2-M1 is able to eradicate biofilms formed during human infection and caused by an antibiotic resistant Gram-negative pathogen. These data fully support the potential therapeutic application of amurin peptides in treating antibiotic resistant Gram-negative infections.

Conclusion

We are glad to see that the company has a plan in place for the Phase 3 clinical trial of exebacase and that positive results from a single trial will be sufficient to support a biologics licensing application (BLA). We look forward to the initiation of the study and additional guidance on when the interim futility analysis and top line data will be available. With the same primary endpoint as the Phase 2 trial, we believe there is a very high likelihood for success in the Phase 3 trial. Our valuation remains at $4.

PROJECTED FINANCIALS

ContraFect Corp.	2018 A	Q1 A	Q2 A	Q3 E	Q4 E	2019 E	2020 E	2021 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	$22.4	$4.1	$4.8	$5.2	$5.3	$19.4	$24.0	$28.0
General & Administrative	$8.7	$2.3	$2.6	$2.3	$2.3	$9.5	$9.5	$10.0
Other Expenses	$0	$0	$0	$0	$0	$0	$0	$0
Operating Income	($31.1)	($6.4)	($7.4)	($7.5)	($7.6)	($28.9)	($33.5)	($38.0)
Operating Margin		-	-	-	-			
Non-Operating Expenses (Net)	($6.6)	$17.9	($1.3)	$0.0	$0.0	$16.7	$0.0	$0.0
Pre-Tax Income	($37.7)	$11.6	($8.7)	($7.5)	($7.6)	($12.2)	($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)**	**$11.6**	**($8.7)**	**($7.5)**	**($7.6)**	**($12.2)**	**($33.5)**	**($38.0)**
Net Margin		-	-	-	-			
Reported EPS	**($0.50)**	**$0.15**	**($0.11)**	**($0.08)**	**($0.08)**	**($0.14)**	**($0.36)**	**($0.39)**
YOY Growth		-	-	-	-			
Basic Shares Outstanding	76.1	79.4	79.4	90.0	91.0	85.0	92.0	98.0

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

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