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ContraFect Corp. (CFRX-NASDAQ)

CFRX: Phase 3 Trial for Exebacase in MRSA Patients Underway Soon…

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 $3/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 (11/18/19)	$0.29
Valuation	**$3.00**

OUTLOOK

ContraFect Corp. (CFRX) is developing exebacase for the treatment of 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. We anticipate the Phase 3 trial initiating before the end of 2019.

SUMMARY DATA

52-Week High	**$2.47**
52-Week Low	**$0.29**
One-Year Return (%)	**-85.29**
Beta	**0.17**
Average Daily Volume (sh)	**196,602**
Shares Outstanding (mil)	**79**
Market Capitalization ($mil)	**$24**
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 2019 Estimate	**-3.0**
P/E using 2020 Estimate	**-0.8**

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 A	0 A	0 A	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	-$0.07 A	-$0.08 E	-$0.12 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

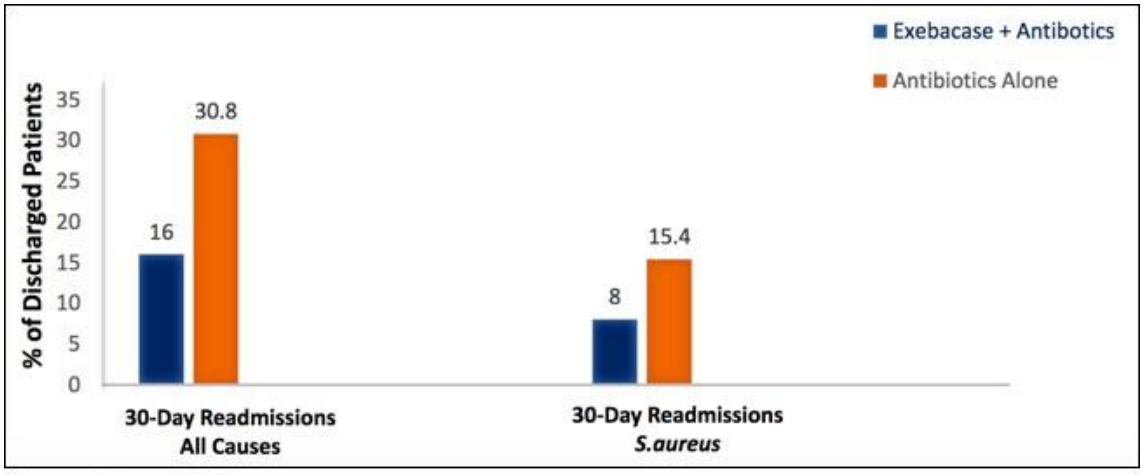
On October 2, 2019, ContraFect Corp. (CFRX) announced that following a successful 'end-of-Phase 2' meeting with the FDA the company is planning to conduct a single Phase 3 clinical trial of exebacase in patients with *Staphylococcus aureus* bacteremia, including right-sided endocarditis. The randomized, double blind, placebo controlled DISRUPT (Direct Lysis of *Staph aureus* Resistant Pathogen Trial) 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.

Presentations at ID Week 2019

In October 2019, ContraFect presented a late breaker oral presentation on the reduction of health resource utilization among MRSA patients treated with exebacase during the Phase 2 trial at ID Week 2019. In addition, the company presented posters on antimicrobial susceptibility of *S. aureus* isolates taken from patients in the Phase 2 trial and the results of several preclinical efficacy studies.

Exebecase (EXE) Reduced Length of Stay and 30-Day Readmission Rates for US Patients with Methicillin Resistant Staphylococcus aureus (MRSA) Bacteremia Including Endocarditis Compared to Standard of Care Antibiotics (SoC) Alone in a Phase 2 Study (slides)

MRSA infections result in much higher hospital costs ($113,852) compared to methicillin-sensitive *S. aureus* (MSSA) infections ($42,137) (Ben-David *et al*., 2009), thus new strategies to combat MRSA infections are warranted both from a healthcare and health economics perspective. Treatment of MRSA infections with exebacase plus SoC antibiotics decreased the median length of hospital stay from 10 days to 6.0 days compared to treatment with SoC antibiotics alone. In addition, treatment with exebacase also lowered 30-day readmission rates, both all cause and due to *S. aureus*, as shown in the following figure. Thus, in addition to being more efficacious, exebacase may offer a health savings aspect to the treatment of MRSA, which could appeal to both payers and physicians.



Source: Cassino *et al.*, 2019

Exebacase (Lysin CF-301) Activity Against *Staphylococcus aureus (S. aureus*) Isolates from Bacteremic Patients Enrolled in a Phase 2 Study (CF-301-102) (poster)

The purpose of this study was to determine the range of minimum inhibitory concentration (MIC) values for exebacase against *S. aureus* isolates from the Phase 2 trial. Isolates were taken from 115 patients and MICs were determined through standard testing techniques. The following table shows the range of MICs for each of the isolates, with the majority having a MIC of 0.5 or 1 μg/mL. Prior testing showed that exebacase was expected to be active against *S. aureus* strains with MICs ≤ 2 μg/mL.

Table 1. Exebacase MICs against *S. aureus* baseline isolates from Ph2 Study CF-301-102

Organism	N	MIC (μg/mL)					MIC_{50}	MIC_{90}
		0.125	0.25	0.5	1	2		
All *S.aureus*	116*	1	13	49	43	10	0.5	1
MSSA	74	1	8	34	26	5	0.5	1
MRSA	42	0	5	15	17	5	1	2

*One patient had both MRSA and MSSA and was counted in both subgroups

Source: Anastasiou *et al.*, 2019

The following table shows the number of patients with clinical response at the different MIC levels. Clinical response rates were higher in the exebacase + SoC compared to the SoC alone groups at each MIC level.

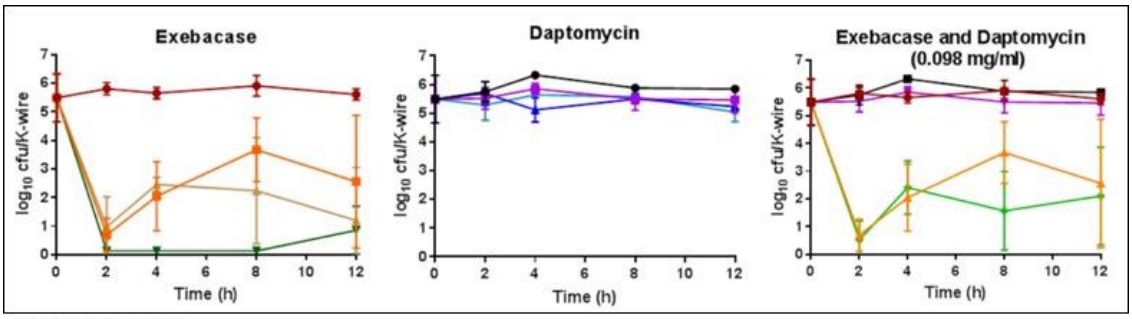
Table 2. Clinical Response at Day 14 by Baseline EXE MIC - MRSA

MIC (μg/mL)	Number of patients exhibiting clinical response (%) in the exebacase and placebo groups	
	EXE + SoC	SoC alone
0.12	0	0
0.25	3/3 (100)	0/2 (0)
0.5	9/11 (81.8)	2/4 (50.0)
1.0	6/9 (66.7)	3/8 (37.5)
2.0	1/3 (33.3)	0/2 (0)

Source: Anastasiou *et al.*, 2019

Activity of Exebacase (CF-301) Against Methicillin-Resistant *Staphylococcus aureus* (MRSA) Biofilms on Orthopedic Kirschner Wires (poster)

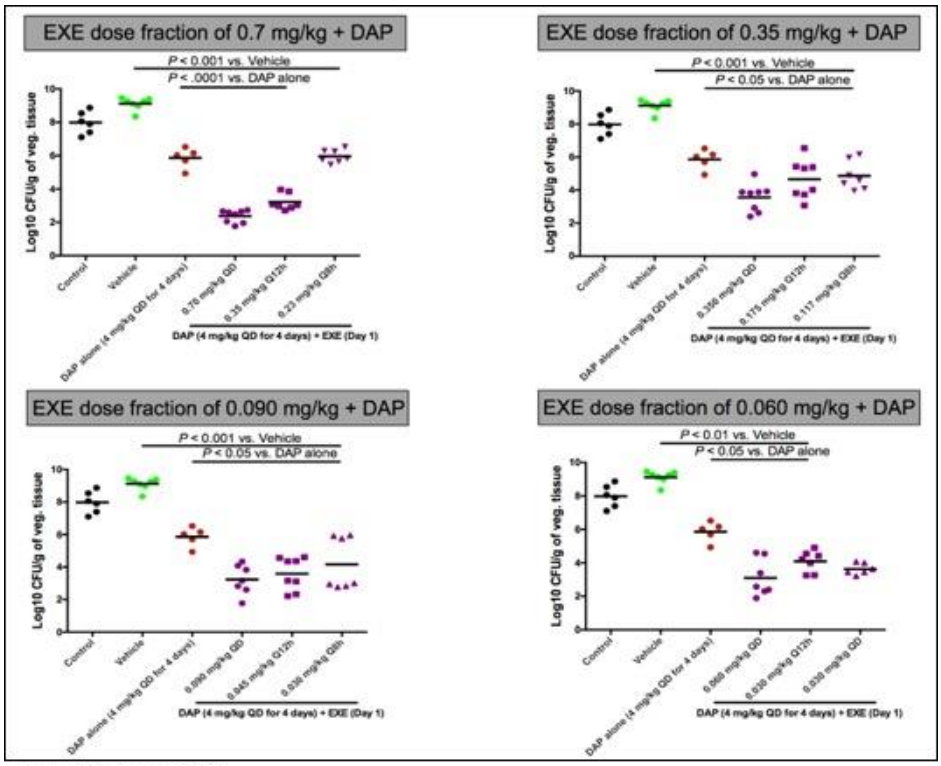
Biofilms produced by *S. aureus* help the organism to evade the immune system and serves as a barrier to antibiotic treatment. Surgery and long-term antibiotic therapy are typically necessary to clear biofilms. The purpose of this study was to determine if biofilms grown from a clinical isolate taken from a patient in the Phase 2 trial could be cleared by exebacase, daptomycin, or a combination of the two. Biofilms were grown on stainless steel Kirschner wires and then treated with varying concentrations of exebacase, daptomycin, or a combination therapy for 2, 4, 8, or 12 hours. The following figure shows that exebacase quickly cleared the biofilm, however daptomycin showed no effect. Thus, local application of exebacase on a biofilm could be a potential therapeutic option for these difficult to treat infections.



Source: Karau *et al.*, 2019

Impact of Dose-Administration Strategies of the Antistaphylococcal Lysin Exebacase, (CF-301), in Addition to Daptomycin (DAP) in an Experimental Infective Endocarditis (IE) Model due to Methicillin-Resistant *Staphylococcus aureus* (MRSA) (poster)

This study was undertaken to determine the efficacy of daptomycin alone or daptomycin plus exebacase administered using various dosing regimens in a rabbit model of infective endocarditis. The following charts show that all exebacase doses given along with daptomycin significantly reduced MRSA better than daptomycin alone, and that giving exebacase as a single dose trended towards better efficacy than the same total exebacase dose given fractionated at 12-hour or 8-hour intervals, however this difference wasn't statistically significant.



Source: Xiong *et al.*, 2019

Financial Update

On November 12, 2019, ContraFect announced financial results for the third quarter of 2019. As expected, the company did not report any revenues for the third quarter of 2019. Net loss for the third quarter of 2019 was $5.4 million, or $0.07 per share, compared to a net loss of $4.4 million, or $0.06 per share, for the third quarter of 2018. R&D expenses totaled $5.3 million for the third quarter of 2019 compared to $5.7 million for the third quarter of 2018. The decrease was primarily due to decreased spending associated with the Phase 2 trial of exebacase partially offset by increased manufacturing costs to support the upcoming Phase 3 clinical trial. G&A expenses were $2.4 million for the third quarter of 2019 compared to $2.1 million for the third quarter of 2018. The increase was primarily due to increased legal and professional fees along with increased non-cash share-based compensation expenses.

As of Sep. 30, 2019, ContraFect had approximately $10.5 million in cash, cash equivalents, and marketable securities. We estimate that this will be sufficient to fund operations into the first quarter of 2020, however the company will need to raise substantial additional capital in order to conduct the Phase 3 clinical trial. As of Nov. 8, 2019, the company had approximately 79.4 million shares outstanding and when factoring in warrants and stock options a fully diluted share count of approximately 122.1 million shares.

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. Due to the continued decrease in the share price, which increases our estimated dilution for the next financing, we have decreased our valuation slightly to $3 per share.

PROJECTED FINANCIALS

ContraFect Corp.	2018 A	Q1 A	Q2 A	Q3 A	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	$5.3	$5.3	$19.5	$24.0	$28.0
General & Administrative	$8.7	$2.3	$2.6	$2.4	$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)	($7.6)	($7.6)	($29.0)	($33.5)	($38.0)
Operating Margin		-	-	-	-			
Non-Operating Expenses (Net)	($6.6)	$17.9	($1.3)	$2.3	$0.0	$19.0	$0.0	$0.0
Pre-Tax Income	($37.7)	$11.6	($8.7)	($5.4)	($7.6)	($10.0)	($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)**	**($5.4)**	**($7.6)**	**($10.0)**	**($33.5)**	**($38.0)**
Net Margin		-	-	-	-			
Reported EPS	**($0.50)**	**$0.15**	**($0.11)**	**($0.07)**	**($0.08)**	**($0.12)**	**($0.36)**	**($0.39)**
YOY Growth		-	-	-	-			
Basic Shares Outstanding	76.1	79.4	79.4	79.4	91.0	82.3	92.0	98.0

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

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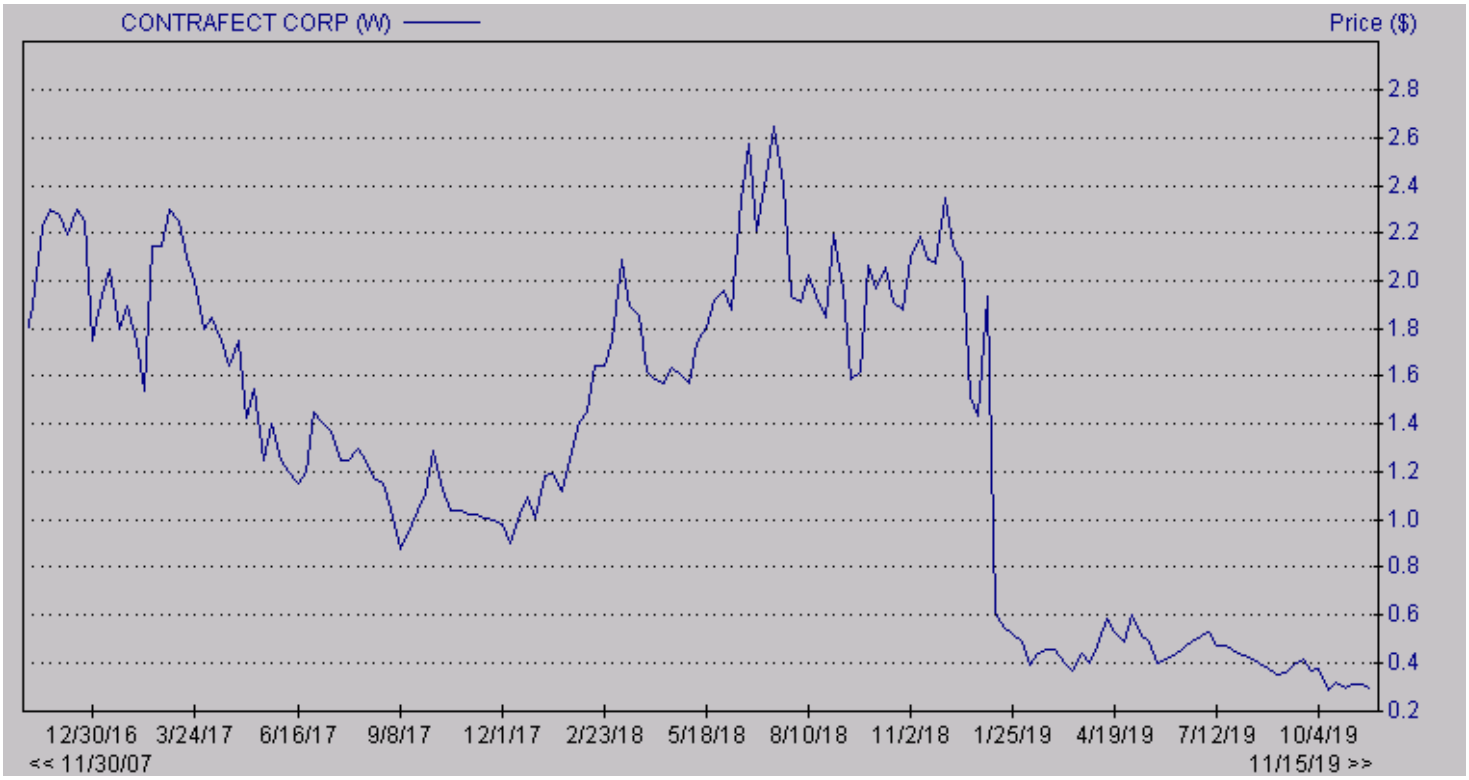
HISTORICAL STOCK PRICE



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