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ContraFect Corp. (CFRX-NASDAQ)

CFRX: New Data on Exebacase Shows Rapid Resolution of Symptoms in Phase 2 Trial…

Based on our updated probability adjusted DCF model that takes into account potential future revenues from CF-301 in bacteremia along with the lysin pipeline, our valuation of CFRX is $23/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 (10/12/21)	$4.01
Valuation	**$23.00**

OUTLOOK

On October 4, 2021, ContraFect Corp. (CFRX) announced new data from the company's Phase 2 clinical trial of exebacase showing rapid symptom resolution in patients with *Staphylococcus aureus* bacteremia was presented as a Late Breaker oral presentation at IDWeek™ 2021. The data showed that the median time to resolution of at least one symptom present at baseline was 3 days for exebacase plus standard of care (SOC) antibiotics-treated patients (n=53) compared to 6 days for patients treated with SOC alone (n=33). These data held true whether the patient had methicillin sensitive *S. aureus* (MSSA) or methicillin-resistant *S. aureus* (MRSA). These data further validate the use of exebacase in addition to SOC antibiotics in patients with difficult to treat S. aureus bacteremia infections.

SUMMARY DATA

52-Week High	**$6.68**
52-Week Low	**$3.19**
One-Year Return (%)	**-28.39**
Beta	**0.86**
Average Daily Volume (sh)	**97,444**
Shares Outstanding (mil)	**39**
Market Capitalization ($mil)	**$158**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**59**
Insider Ownership (%)	**4**
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	**-3.9**
P/E using 2020 Estimate	**-4.1**

Risk Level	**Above Avg.**
Type of Stock	**Small-Blend**
Industry	**Med-Drugs**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2020	0 A	0 A	0 A	0 A	0 A
2021	0 A	0 A	0 E	0 E	0 E
2022					0 E
2023					0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2020	-$0.49 A	-$0.88 A	$0.12 A	-$0.23 A	-$1.24 A
2021	-$0.18 A	-$0.14 A	-$0.24 E	-$0.26 E	-$0.82 E
2022					-$1.02 E
2023					-$1.00 E

Business Update

Rapid Resolution of Symptoms in Phase 2 Trial

On October 4, 2021, ContraFect Corp. (CFRX) announced new data from the company's Phase 2 clinical trial of exebacase showing rapid symptom resolution in patients with *Staphylococcus aureus* bacteremia was presented as a Late Breaker oral presentation at IDWeek™ 2021.

The Phase 2 study 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. Please see our previous reports (here and here) for an overview of results from the trial.

The new data presented at IDWeek™ 2021 concerned symptom resolution in the modified intent-to-treat (mITT) population (n=71 exebacase+SOC; n=45 SOC alone). The results showed that 86 patients with S. aureus bacteremia had at least one symptom at baseline (n=53 exebacase+SOC; n=33 SOC alone). The symptoms resolved in the majority of these patients (94.3% exebacase+SOC; 87.9% SOC alone). The percentage of patients whose symptoms resolved was similar for those with methicillin-resistant S. aureus (MRSA) infections as well (94.4% exebacase+SOC; 81.8% SOC alone). Where exebacase differentiated itself was in the median time to resolution. For the mITT group, the median time to symptom resolution for the exebacase+SOC group was 3 days (95% CI 3-7) compared with 6 days (95% CI 3-7) for the SOC alone group. Similar results were seen for the MRSA subgroup. The results are summarized in the following table.

	All Patients		MRSA Patients	
	Exebacase + SOCA (N=71) n (%)	**SOCA Alone (N=45) n (%)**	**Exebacase + SOCA (N=27) n (%)**	**SOCA Alone (N=16) n (%)**
Patients with at least one symptom	**53 (74.6)**	**33 (73.3)**	**18 (66.7)**	**11 (68.8)**
Achieved symptom resolution	50 (94.3)	29 (87.9)	**17 (94.4)**	**9 (81.8)**
Time to Symptom Resolution, Median [95% CI]	3 days [2,7]	6 days [3, 7]	**3 days (2, 9)**	**7 days (2, 28)**

Source: ContraFect Corp.

Coupled with the previously disclosed data from the trial showing a 42.8% higher clinical responder rate at Day 14 with exebacase in the prespecified MRSA subgroup, the newly presented data on reduction in the median time to symptom resolution shows that rapid bacteriolysis caused by exebacase may translate into a clinical benefit for patients with *S. aureus* bacteremia.

In Vitro *Activity of Exebacase Against* S. Aureus *Clinical Isolates*

In addition to the oral presentation at IDWeek™ 2021, ContraFect also presented a poster on the *in vitro* activity of exebacase against clinical isolates of *S. aureus* collected during the COVID-19 pandemic. This work was done as part of the SENTRY Antimicrobial Surveillance Program. A total of 2,849 pathogens were collected from blood

cultures of patients suffering from bloodstream infections at 29 U.S. medical centers (20 states) during 2020. Of the 2,849 pathogens collected, 666 (23.4%) were identified as *S. aureus* and included in the study. This is in line with the previous five years showing *S. aureus* represented approximately 24% of the causative pathogens of bloodstream infections dating back to 2016. The following table shows the minimum inhibitory concentration (MIC) distribution for the 666 *S. aureus* isolates. Exebacase inhibited 100% of *S. aureus* isolates at MIC values ≤ 1 μg/mL and showed equivalent MIC results for both MSSA and MRSA strains.

S. aureus/ Subset (no. of isolates)	No. and cumulative % of isolates inhibited at MIC (μg/mL) of:							MIC_{50}	MIC_{90}
	≤0.03	0.06	0.12	0.25	0.5	1	2		
All[a] (666)		1 0.2	0 0.2	43 6.6	577 93.2	45 100.0		0.5	0.5
Methicillin-susceptible (409)			0 0.0	29 7.1	352 93.2	28 100.0		0.5	0.5
Methicillin-resistant (257)		1 0.4	0 0.4	14 5.8	225 93.4	17 100.0		0.5	0.5
MDR (160)		1 (0.6)	0 (0.6)	10 (6.9)	137 (92.5)	12 (100.0)		0.5	0.5
Non-MDR (97)				4 (4.1)	88 (94.8)	5 (100.0)		0.5	0.5

[a] Isolates were defined as methicillin-resistant based on an oxacillin resistance phenotype. A multidrug resistance (MDR) phenotype was defined among MRSA isolates when non-susceptible phenotypes were observed for oxacillin and 2 or more of the following agents: ceftaroline, erythromycin, clindamycin, doxycycline, levofloxacin, gentamicin, linezolid, trimethoprim-sulfamethoxazole, daptomycin and vancomycin.

Source: ContraFect Corp.

A series of tests were performed with comparator agents (antibiotics), with most being active (91.7% - 100% susceptible) against the MSSA population, while many had reduced susceptibility against MRSA, including ceftaroline (88.3% susceptible). However, drugs utilized for treating MRSA infections (daptomycin and vancomycin) were active (100% susceptibility) against all isolates.

Of the MRSA isolates, 62.3% of them were classified as multi-drug resistant (MDR). Importantly, exebacase showed equal MIC_{50} and MIC_{90} against the MDR and non-MDR strains ($MIC_{50/90}$, 0.5/0.5 μg/mL). Daptomycin and vancomycin were also active (100% susceptible) against the MDR strains.

These results show that there was not much impact on the etiology of bloodstream infections due to the COVID-19 pandemic and that the occurrence of MRSA infections was actually slightly lower in 2020 (38.6%) compared to previous years (39.5% - 43.1%). It is good to see that exebacase continues to be active against clinical isolates, regardless of resistance phenotype, particularly since the study included clinical isolates recovered from patients that are reflective of the patient cohort in the company's ongoing Phase 3 clinical trial.

Conclusion

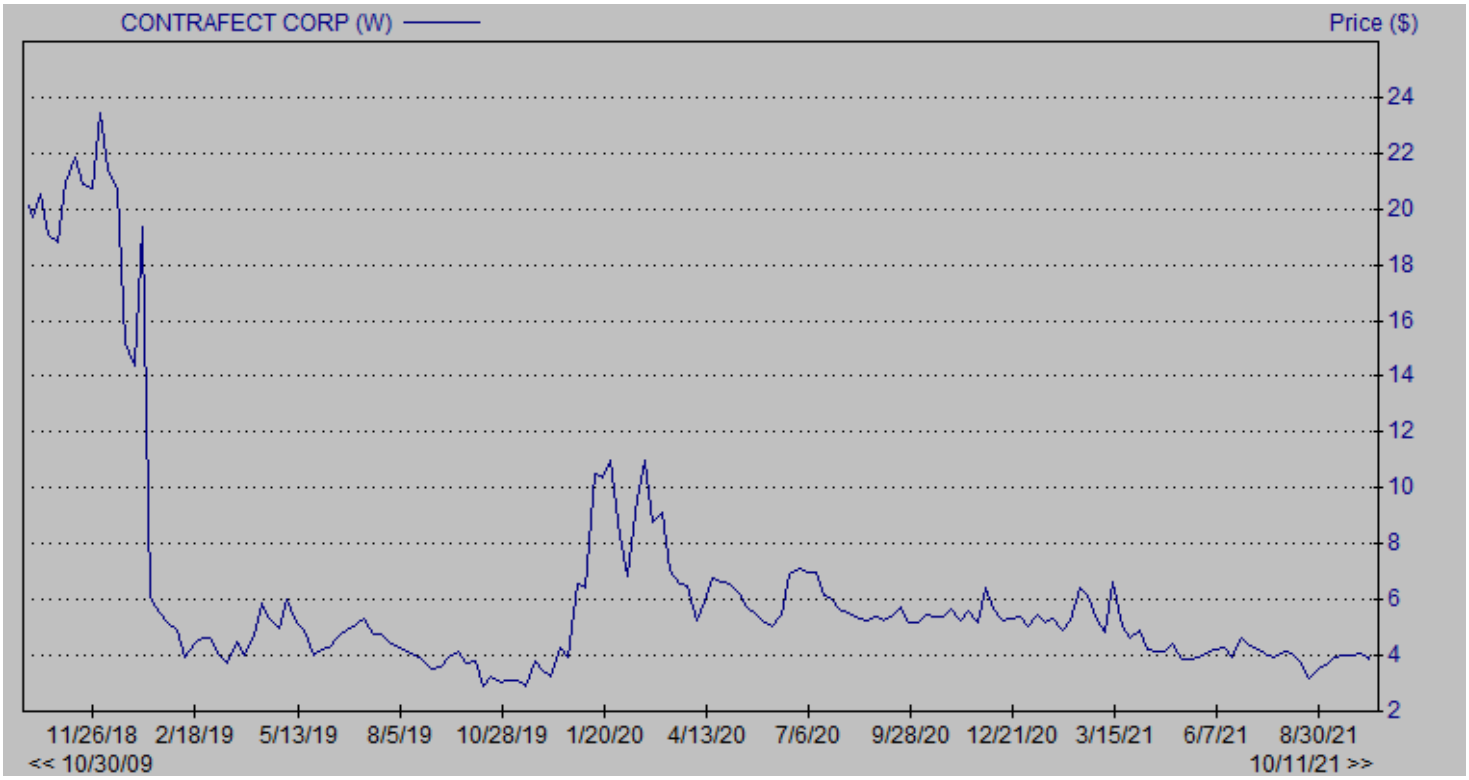
The data presented by ContraFect at IDWeek™ 2021 support the continued development of exebacase as a treatment for bloodstream infections caused by *S. aureus*. The ongoing Phase 3 DISRUPT (Direct Lysis of *Staph aureus* Resistant Pathogen Trial) trial is continuing to enroll patients and we look forward to an update from the company on when the preplanned interim futility analysis will take place, which is scheduled to occur after the first 60% of patients are enrolled in the trial and evaluable for efficacy. With no changes to our model our valuation remains at $23 per share.

PROJECTED FINANCIALS

ContraFect Corp.	2020 A	Q1 A	Q2 A	Q3 E	Q4 E	2021 E	2022 E	2023 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	$22.6	$8.0	$7.8	$6.5	$7.0	$29.3	$30.0	$35.0
General & Administrative	$11.6	$2.8	$2.9	$3.6	$3.9	$13.2	$15.0	$17.0
Other Expenses	$0	$0	$0	$0	$0	$0	$0	$0
Operating Income	($34.2)	($10.8)	($10.7)	($10.1)	($10.9)	($42.5)	($45.0)	($52.0)
Operating Margin		-	-	-	-			
Non-Operating Expenses (Net)	$6.1	$5.6	$5.3	$0.5	$0.5	$11.9	$2.0	$2.0
Pre-Tax Income	($28.2)	($5.2)	($5.4)	($9.6)	($10.4)	($30.6)	($43.0)	($50.0)
Income Taxes Paid	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	**($28.2)**	**($5.2)**	**($5.4)**	**($9.6)**	**($10.4)**	**($30.6)**	**($43.0)**	**($50.0)**
Net Margin		-	-	-	-			
Reported EPS	**($1.24)**	**($0.18)**	**($0.14)**	**($0.24)**	**($0.26)**	**($0.82)**	**($1.02)**	**($1.00)**
YOY Growth		-	-	-	-			
Basic Shares Outstanding	22.8	29.0	39.3	40.0	40.5	37.2	42.0	50.0

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

HISTORICAL STOCK PRICE



Source: Zacks Investment Research

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