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ContraFect Corp. (CFRX-NASDAQ)

CFRX: Enrollment for Phase 2 Trial of CF-301 Complete; Data in 4Q18…

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 $6/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 (09/24/18)	$1.62
Valuation	**$6.00**

OUTLOOK

ContraFect Corp. (CFRX) recently announced that the company has completed enrollment of the Phase 2 clinical trial of CF-301 (exebacase) in patients with bacteremia caused by *Staphylococcus aureus*. We anticipate topline results in the fourth quarter of 2018.

The company recently presented data at the ESCMID/ASM Conference on Drug Development to Meet the Challenge of Antimicrobial Resistance that showed CF-301 can resensitize methicillin-resistant *S. aureus* (MRSA) to different penicillin derivatives both *in vitro* and in a rabbit endocarditis model. The ability of CF-301 to make resistant strains susceptible to antibiotics to which they had developed resistance is an important new observation and could represent a novel mechanism to fight the rise in antibiotic resistant bacteria.

SUMMARY DATA

52-Week High	**$2.82**
52-Week Low	**$0.89**
One-Year Return (%)	**55.77**
Beta	**-0.45**
Average Daily Volume (sh)	**152,922**
Shares Outstanding (mil)	**79**
Market Capitalization ($mil)	**$129**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**55**
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 E	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	-$0.09 E	-$0.09 E	-$0.70 E
2019					-$0.36 E
2020					-$0.37 E

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Business Update

Phase 2 Trial of CF-301 Fully Enrolled

On September 6, 2018, ContraFect Corp. (CFRX) announced that the Phase 2 trial of CF-301 (exebacase) is fully enrolled. CF-301 is the company's lead lysin product candidate being tested for the treatment of bacteremia, including those with endocarditis, caused by both methicillin-resistant (MRSA) and methicillin-sensitive (MSSA) strains of *Staphylococcus aureus*. The trial is an international, multicenter, randomized, double blind, placebo controlled study with a superiority comparison between CF-301 or placebo combined with the standard of care antibiotics. The study was expected to enroll approximately 115 patients randomized 3:2 to receive a single dose of 0.25 mg/kg CF-301 administered via a two-hour infusion or placebo along with standard of care antibiotics. The primary endpoint of the study will be early clinical response. Safety, tolerability, and pharmacokinetics will also be examined along with additional exploratory clinical and health economic endpoints. We anticipate topline results in the fourth quarter of 2018.

CF-301 Resensitizes Antibiotic Resistant Species

In September 2018, ContraFect presented new data for CF-301 at the European Society for Clinical Microbiology and Infectious Diseases (ESCMID) / American Society for Microbiology (ASM) Conference on Drug Development to Meet the Challenge of Antimicrobial Resistance. The data showed that CF-301 is able to resensitize antibiotic resistant strains to be susceptible to the antibiotic to which they had developed resistance. The following table shows data from a checkerboard assay that shows the potency of CF-301 with different antibiotics (oxacillin, OXA; nafcillin, NAF; cefazolin, CFZ) along with their individual activities against nine MRSA strains. The minimum inhibitory concentration (MIC) is shown for each individual component ($MIC_{initial}$) and in combination (MIC_{final}). MIC values $\leq$ 2.0 denote sensitivity while values $\geq$ 4.0 denote resistance. Fractional inhibitory concentration index (FICI) values $\leq$ 0.5 denote synergy. All combinations of CF-301 and the tested β-lactam antibiotics showed synergy.

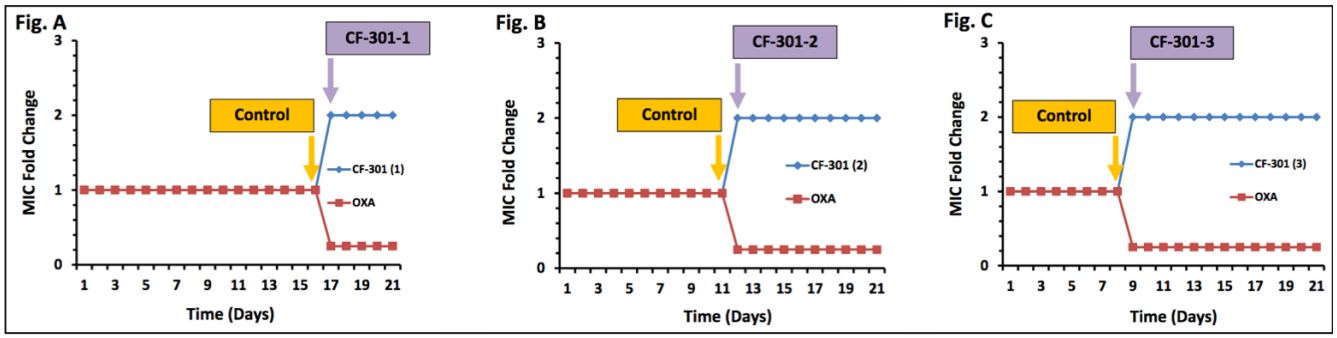
TABLE 1.

		Antimicrobial Agents					
Strain	**MIC & FICI**	**CF-301**	**OXA**	**CF-301**	**NAF**	**CF-301**	**CFZ**
NRS 100	$MIC_{initial}$	1	256	1	64	1	256
	MIC_{final}	0.25	2	0.25	1	0.25	1
	FICI	0.258		0.266		0.254	
ATCC 43300	$MIC_{initial}$	1	8	1	2	1	16
	MIC_{final}	0.25	0.5	0.125	0.25	0.125	4
	FICI	0.313		0.250		0.133	
HPV 107	$MIC_{initial}$	1	8	1	2	1	16
	MIC_{final}	0.25	0.5	0.25	0.25	0.125	2
	FICI	0.313		0.375		0.250	
CAIRD 426	$MIC_{initial}$	1	4	1	16	1	8
	MIC_{final}	0.25	1	0.25	1	0.25	0.5
	FICI	0.313		0.313		0.313	
JMI 227	$MIC_{initial}$	1	16	1	4	1	2
	MIC_{final}	0.25	1	0.25	0.5	0.25	0.5
	FICI	0.313		0.375		0.500	
JMI 1280	$MIC_{initial}$	1	256	1	256	1	32
	MIC_{final}	0.25	1	0.25	2	0.25	0.5
	FICI	0.254		0.258		0.266	
JMI 4789	$MIC_{initial}$	1	64	1	4	1	4
	MIC_{final}	0.25	2	0.125	0.5	0.125	1
	FICI	0.281		0.250		0.375	
MW2	$MIC_{initial}$	1	64	2	4	1	4
	MIC_{final}	0.25	2	0.5	0.031	0.125	1
	FICI	0.281		0.258		0.375	
ATCC 33591	$MIC_{initial}$	1	256	1	64	1	128
	MIC_{final}	0.25	1	0.125	2	0.25	0.5
	FICI	0.254		0.156		0.254	

Oh *et al*., 2018

Key: resensitization | synergy

A 21-day *in vitro* serial passage assay was performed to determine the effect of CF-301 treatment on OXA MIC values in MRSA strain MW2. Previously, the company presented data showing that as the MIC value for CF-301 increased (not by any more than 2-fold) the MIC value for OXA decreased. This data was recapitulated in this study as shown below.



Source: Oh *et al.*, 2018

The isolates denoted by the purple boxes above were subjected to sequencing analysis to determine specific mutations that may be responsible for the increased susceptibility to OXA. The following table shows that three different mutations were identified in the *murA*, *lyrA*, and *oatA* genes, and these mutations were confirmed as causative through a two-step allelic exchange process.

TABLE 2. Mutations associated with CF-301-mediated reductions in OXA MICs (SNP/INDEL analysis of in vitro-derived isolates)

Reference Position(s)[a]	Overlapping Annotation[b]	Ref	Allele	Amino Acid Change	CF-301 Control	CF-301 1	CF-301 2	CF-301 3
2180631	*murA*	G	T	R95S	-	-	+	-
2403752	*lyrA*	C	A	Y245*	-	-	-	+
2658191	*oatA*	C	A	*oatA* promoter	-	+	-	-

[a]Position in the reference genome of *Staphylococcus aureus* MW2 (GenBank accession: NC_003923.1)

Oh *et al.*, 2018

[b]Annotated open reading frames overlapping computationally predicted polymorphisms

The *in vitro* effects seen in the serial passage assay were recapitulated in an *in vivo* rabbit infective endocarditis model, where treatment with CF-301 resulted in up to 16-fold reductions in MIC values for OXA, as shown in the following table. The MIC for OXA against MW2 (the strain used in the assay) is 32 μg/mL.

Treatment Groups[a]	Log_{10} CFU/g of Vegetation[b]	n[c]	CF-301 MIC (μg/mL)[d] 0.25	0.5	1	2	4	OXA MIC (μg/mL)[e] ≤2	4	8	16	32	64
Pre-Treatment Control	7.02±1.47	24			24							24	
Buffer treatment Control	7.26±1.54	32			31	1				2		30	
CF-301 (1.4)	8.24±0.02	24			24			7				17	
CF-301 (0.7)	7.93±0.12	24		1	23						1	23	
CF-301 (0.35)	8.17±0.58	24		3	21			6				18	
CF-301 (0.18)	8.65±0.58	16			16							16	

[a]Number in parenthesis represents dose in mg/kg
[b]Limit of detection is indicated by the less than sign for each group
[c]Number of isolates analyzed in MIC assays from each group
[d]The CF-301 MIC of *S. aureus* strain MW2 is 1 μg/mL
[e]The OXA MIC of *S. aureus* strain MW2 is 32 μg/mL

CF-301 MICs are stable

CF-301 exposure resulted in increased OXA susceptibility

Oh *et al.*, 2018

Two of the mutants that exhibited 32-fold decreases in OXA MIC were sequenced to identify mutations that may be responsible for the change in activity. The following table shows four mutations that were identified that may be responsible for the decrease in OXA MIC among the mutants. In addition, both mutants had a loss of SCC*mec*, a mobile genetic element that can be transferred within the genome and between species, however the actual mutation(s) have yet to be identified.

TABLE 4. Mutations associated with CF-301-mediated reductions in OXA MICs (SNP/INDEL analysis of in vivo-derived isolates)

Reference Position(s)[a]	Overlapping Annotation[b]	Ref	Allele	AA Change	MIC (µg/mL)									
					Control		Control 2		Control 3		Mutant 1		Mutant 2	
					CF-301	OXA	CF-301	OXA	CF-301	OXA	CF-301	OXA	CF-301	OXA
					1	64	2	32	2	64	2	1	1	1
2492859	*hlgCB* (near)	T	C		-		-		-		+		+	
1366472	*mprF*	T	A	L291I	-		-		-		+		-	
704001	*graR*	T	G	I158S	-		-		-		-		+	
34167	*rlmH*	G	A	K159R	-		-		-		+		+	
SCC*mec*			ΔSCC*mec*		-		-		-		+		+	

Oh *et al*., 2018

The key takeaway from the preceding data presented by ContraFect is that CF-301 (and potentially lysins as a group) are able to resensitize antibiotic resistant bacteria to the antibiotic to which they developed resistance. This could be a huge advancement in the battle against antibiotic resistant bacteria and potentially increase the value of the lysin technology. In addition, this could be applicable to the clinic in that CF-301 may make antibiotic resistant infections more amenable to conventional antibiotic treatment when used as a co-therapy.

Conclusion

We're glad to see that the Phase 2 trial is fully enrolled and we are excited to see the results in the fourth quarter of 2018. The *in vitro* and *in vivo* data that ContraFect has presented at various conferences over the past couple of years has given us confidence that the Phase 2 trial will be a success. Our valuation currently stands at $6 and we believe investors would be well served to take a closer look at the company in the lead up to the Phase 2 data release.

PROJECTED FINANCIALS

ContraFect Corp.	2017 A	Q1 A	Q2 A	Q3 E	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	$4.8	$4.9	$19.7	$19.5	$20.0
General & Administrative	$9.2	$2.2	$2.2	$2.4	$2.4	$9.3	$10.0	$10.5
Other Expenses	$0	$0	$0	$0	$0	$0	$0	$0
Operating Income	($26.6)	($7.0)	($7.5)	($7.2)	($7.3)	($29.0)	($29.5)	($30.5)
Operating Margin		-	-	-	-			
Non-Operating Expenses (Net)	$11.0	($12.1)	($12.6)	$0.0	$0.0	($24.8)	($0.4)	($0.4)
Pre-Tax Income	($15.5)	($19.1)	($20.1)	($7.2)	($7.3)	($53.7)	($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)**	**($7.2)**	**($7.3)**	**($53.7)**	**($29.9)**	**($30.9)**
Net Margin		-	-	-	-			
Reported EPS	**($0.28)**	**($0.26)**	**($0.27)**	**($0.09)**	**($0.09)**	**($0.70)**	**($0.36)**	**($0.37)**
YOY Growth		-	-	-	-			
Basic Shares Outstanding	55.6	73.7	73.7	79.0	79.5	76.5	82.0	84.0

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

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