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ContraFect Corp. (CFRX-NASDAQ)

CFRX: Multiple Presentations on CF-301 at ECCMID…

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 $7/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 (05/14/18)	$1.74
Valuation	**$7.00**

OUTLOOK

In April 2018, Contrafect Corp. (CFRX) presented data on its lead drug candidate CF-301 concerning *in vitro*, *in vivo*, and microbiologic surveillance studies. The studies involved CF-301's synergy with standard of care antibiotics, anti-biofilm activity, and activity against multiple clinical isolates of *Staphylococcus aureus* collected from centers across Europe.

ContraFect is continuing to enroll patients in the Phase 2 clinical trial of CF-301 in patients with bacteremia, including those with endocarditis, which is caused by both methicillin-resistant (MRSA) and methicillin-sensitive (MSSA) strains of *S. aureus*. We anticipate topline results in 4Q18.

SUMMARY DATA

52-Week High	**$2.17**
52-Week Low	**$0.88**
One-Year Return (%)	**12.26**
Beta	**-0.56**
Average Daily Volume (sh)	**64,125**
Shares Outstanding (mil)	**74**
Market Capitalization ($mil)	**$128**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**62**
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	**Above Avg.**
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 E	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	-$0.10 E	-$0.10 E	-$0.10 E	-$0.51 E
2019					-$0.36 E
2020					-$0.37 E

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Business Update

Multiple Presentations on CF-301 at ECCMID

In April 2018, ContraFect Corp. (CFRX) had multiple presentations at the 28th European Congress of Clinical Microbiology and Infectious Diseases (ECCMID) on the company's lead drug candidate CF-301. A summary of each of the posters is presented below.

Translational study of the antibiofilm activity of lysin CF-301 in an infected hemodialysis catheter from patient with suspected *Staph aureus* bacteremia

This study was performed to determine if CF-301 could eradicate a biofilm resulting from infection with multiple staphylococcal species that formed on a catheter in a hemodialysis patient. The catheter was removed as part of the patient's care and segmented into different treatment groups: CF-301, daptomycin, or CF-301 + daptomycin with each compound used at concentrations of 1 μg/mL (a clinically relevant dose), 10 μg/mL, or 100 μg/mL. Following 18 hours of treatment the catheter pieces were homogenized for quantitative plating. The following table shows that CF-301 at 1 μg/mL, but not daptomycin at 1 μg/mL, was able to eradicate the biofilm. This is the first study to show CF-301's ability to eradicate a biofilm formed in a patient.

Treatment Groups	CF-301 (μg/mL)	DAP (μg/mL)	Log_{10} CFU/g of Catheter
Pretreatment Control[a]	n.a.	n.a.	2.94
Buffer Control[b]	0	0	2.88
CF-301 Alone	1	0	<LOD[c]
	10	0	<LOD
	100	0	<LOD
DAP Alone	0	1	3.76
	0	10	<LOD
	0	100	<LOD
CF-301+DAP (Combos)[d]	1	1	<LOD

[a]The pretreatment group was used to determine baseline CFUs prior to any treatment, thus the indicated treatments are "not applicable" (n.a.)
[b]"0" is used to indicate that no CF-301 or DAP was used in the Buffer Control. The Buffer Control is treated with Lactated Ringer's solution alone.
[c]The limit of detection (LOD) is 0.7 Log_{10} CFU/g
[d]All combinations with CF-301 at 100, 10, and 1 μg/mL yielded no CFUs

Source: Oh *et al.*, 2018

Lysin CF-301 exhibits a low propensity for decreased susceptibility and prevents daptomycin resistance in a rabbit model of *Staph aureus* infective endocarditis

This study involved the use of an aortic valve infective endocarditis (IE) model in rabbits using methicillin-resistant *Staphylococcus aureus* (MRSA) strain MW2. Previously, the company had identified a stable 2-fold increase in minimum inhibitory concentration (MIC, the lowest concentration of a drug that will inhibit bacterial growth) in an *in vitro* serial passage assay. This change in MIC was associated with mutations that resulted in reduced growth rate, changes in oxacillin resistance, and a 50% increase in cell wall thickness.

To complement those *in vitro* studies, the company used the MRSA rabbit IE model to assess changes in MIC in animals treated with either CF-301, daptomycin, or a combination of the two. Rabbits with IE were treated for 4 days with daptomycin with or without a single dose of CF-301. *S. aureus* was cultured from the rabbits and assessed for resistance to CF-301, daptomycin, and oxacillin. Similar to the *in vitro*

studies, there was a low propensity for resistance to CF-301 (change in MIC no greater than 2-fold) and CF-301 suppressed daptomycin resistance.

The following two tables show analysis of MIC from isolates recovered from non-selective growth plates and selective growth plates with CF-301 added. The selective growth plates were utilized as a means to enrich for isolates with increased CF-301 MIC. For isolates from the non-selective plates, only two showed a 2-fold increase in MIC, one of which was from the control group of rabbits while the other was from a group of 47 isolates tested from rabbits treated with 0.35 mg/kg CF-301 and daptomycin. In addition, the only daptomycin resistance seen (the red boxes) was with daptomycin treatment alone or daptomycin treatment with the lowest concentration of CF-301 (0.09 mg/kg). Lastly, treatment with CF-301 caused increased susceptibility to oxacillin treatment in certain isolates (purple boxes).

Treatment Groups[a]	Log_{10} CFU/g of Vegetation[b]	n[c]	CF-301 MIC (µg/mL)[d]					DAP MIC (µg/mL)[e]							OXA MIC (µg/mL)[f]					
			0.25	0.5	1	2	4	0.125	0.25	0.5	1	2	4	8	<2	4	8	16	32	64
Pre-Treatment Control	7.02±1.47	24			24					24									24	
Buffer treatment Control	7.26±1.54	32			31	1				30	2						2		30	
DAP (4)	4.03±2.58	24			24							2	22					24		
CF-301 (1.4)	8.24±0.02	24			24				2	20	2				7				17	
CF-301 (0.7)	7.93±0.12	24		1	23				2	20	2							1	23	
CF-301 (0.35)	8.17±0.58	24		3	21					24					6				18	
CF-301 (0.18)	8.65±0.58	16			16				1	15									16	
CF-301 (1.4) DAP (4)	<2.17±0.09	0																		
CF-301 (0.7) DAP (4)	<2.32±0.17	0																		
CF-301 (0.35) DAP (4)	4.02±0.17	47		16	30	1				47									47	
CF-301 (0.18) DAP (4)	3.16±0.33	48			48					48									48	
CF-301 (0.09) DAP (4)	6.27±0.19	60		5	55						3	57							60	

[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 DAP MIC of *S. aureus* strain MW2 is 0.5 µg/mL
[f]The OXA MIC of *S. aureus* strain MW2 is 64 µg/mL
Sterilization

No decreased susceptibility to CF-301

CF-301 suppressed DAP^R

CF-301 exposure resulted in increased OXA susceptibility

Source: Oh *et al.*, 2018

Similar results were seen for isolates plated on the selective growth plates, although there a few more isolates with a modest increase in MIC (≤ 2-fold increase). Daptomycin resistance couldn't be assessed due to the fact that no isolates could be recovered from any of the CF-301/daptomycin combination treated animals. Lastly, some isolates showed increased susceptibility to oxacillin (purple boxes).

Treatment Groups[a]	Log10 CFU/g of Vegetation[b]					n[c]	CF-301 MIC (µg/mL)[d]					DAP MIC (µg/mL)[e]							OXA MIC (µg/mL)[f]					
	0	16	32	64	128		0.25	0.5	1	2	4	0.125	0.25	0.5	1	2	4	8	<2	4	8	16	32	64
Pre-Treatment Control	7.02±1.47	4.3±2.0	<2.3±0.04	<2.3±0.04	<2.3±0.04	19		1	18					19									19	
Buffer treatment Control	7.26±1.54	3.3±1.1	4.9±1.8	3.1±1.6	<2.1±0.1	44			44					44									44	
DAP (4)	4.03±2.58	3.0±2.0	2.9±1.9	2.7±1.4	<2.1±0.1	8		1	7							1	7					8		
CF-301 (1.4)	8.24±0.02	7.1±0.06	5.9±0.03	4.2±1.7	2.8±1.2	24			20	4			3	20	1					3			21	
CF-301 (0.7)	7.93±0.12	6.7±0.1	5.7±1.1	3.8±1.8	<2.1±0.1	24		2	19	3			2	21	1							3	21	
CF-301 (0.35)	8.17±0.58	6.9±0.2	6.4±0.5	5.5±0.6	3.4±1.3	24			22	2			3	21						7			17	
CF-301 (0.18)	8.65±0.58	7.1±0.1	7.1±0.1	6.6±0.9	4.6±0.7	16			14	2				16									16	
CF-301 (1.4) DAP (4)	<2.17±0.09	<2.1±0.1	<2.1±0.1	<2.1±0.1	<2.1±0.1	0																		
CF-301 (0.7) DAP (4)	<2.32±0.17	<2.3±0.1	<2.3±0.1	<2.3±0.1	<2.3±0.1	0																		
CF-301 (0.35) DAP (4)	4.02±0.17	<2.2±0.1	<2.2±0.1	<2.2±0.1	<2.2±0.1	0																		
CF-301 (0.18) DAP (4)	3.16±0.33	<2.2±0.2	<2.2±0.2	<2.2±0.2	<2.2±0.2	0																		
CF-301 (0.09) DAP (4)	6.27±0.19	<2.2±0.1	<2.2±0.1	<2.2±0.1	<2.2±0.1	0																		

[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 treatment group (chosen from the highest CF-301 concentration supporting growth)
[d]The CF-301 MIC of *S. aureus* strain MW2 is 1 µg/mL
[e]The DAP MIC of *S. aureus* strain MW2 is 0.5 µg/mL
[f]The OXA MIC of *S. aureus* strain MW2 is 64 µg/mL
Sterilization

≤2-fold shift increase

Cannot assess suppression of DAP^r

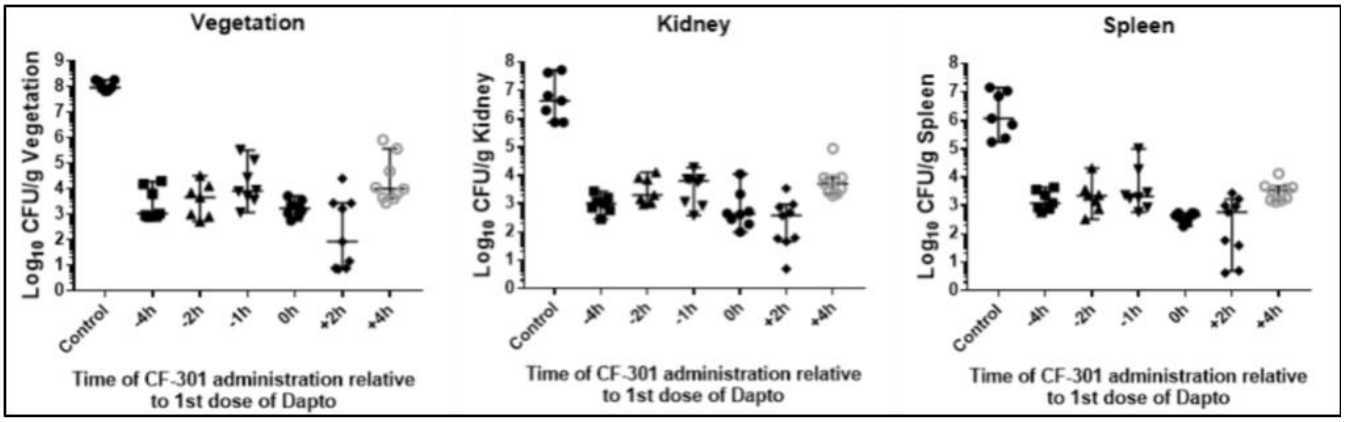
CF-301 exposure resulted in increased OXA susceptibility

Source: Oh *et al.*, 2018

The most important conclusion from this study is that while a modest increase in CF-301 MIC was observed, this likely will not change the susceptibility of those variants to the clinical dose of 0.25 mg/kg being utilized in the ongoing Phase 2 study based on PK modeling.

Optimal timing of the Co-administration of lysin CF-301 with daptomycin in a rabbit model of infective endocarditis due to MRSA

This study was undertaken to determine when best to administer CF-301 in relation to daptomycin in a MRSA IE rabbit model. There were seven groups studied which consisted of a buffer control and CF-301 administered as a single dose either 1 or 4 hours prior to daptomycin treatment, concurrent with daptomycin treatment, or 2 or 4 hours after daptomycin treatment. The following charts show that administration of CF-301 along with daptomycin resulted in a statistically significant reduction in MRSA densities regardless of whether CF-301 was initiated before, during, or after daptomycin administration. While there appears to be a favorable trend for administering CF-301 two hours post daptomycin, none of the CF-301 time points were significantly different from the others and the most important conclusion from this study is that the combination of daptomycin and CF-301 is highly effective against this MRSA strain in the rabbit IE model.



Source: Abdelhady *et al*., 2018

European surveillance study of CF-301 activity against contemporary *Staph aureus* isolates from Italy, Greece, and Hungary

This study was undertaken to determine the effectiveness of CF-301 against *S. aureus* clinical isolates from four centers in Europe. These samples were taken from patients and included both methicillin-sensitive (n = 75) and methicillin-resistant (n=75) thus they represent a "real-world" test of CF-301 activity. The following table shows the MIC_{50} and MIC_{90} values for each of those isolates. All of the strains had MIC_{50} values of 0.5 μg/mL and all strains except for those from Hungary had MIC_{90} values of 0.5 μg/mL. The MSSA strains from Hungary had MIC_{90} values of 1 μg/mL. These values are very similar to what was seen in a previous study of clinical isolates from the U.S. in 2011. We believe that MIC_{90} values of ≤ 1 μg/mL will still be susceptible to the CF-301 clinical dose of 0.25 mg/kg based on PK modeling.

CF-301 vs. *S. aureus* MICs and MIC_{50}/MIC_{90} by Country (μg/mL)

Country	Type	N	0.25	0.5	1	MIC_{50}	MIC_{90}	Range
Greece	MRSA	22	4	13	5	0.5	1.0	0.25 - 1
	MSSA	25	1	16	8	0.5	1	0.25 - 1
Italy	MRSA	28	6	17	5	0.5	1	0.25- 1
	MSSA	27	0	15	12	0.5	1	0.5 – 1
Hungry	MRSA	25	5	18	2	0.5	0.5	0.25 - 1
	MSSA	23	0	15	8	0.5	1	0.5 - 1

Source: Traczewski *et al*., 2018

No Safety Issues Thus Far in Phase 2 Trial of CF-301

ContraFect is currently conducting a Phase 2 clinical trial of CF-301, the company's lead lysin product candidate, in patients with bacteremia, including those with endocarditis, which is 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 will include 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. The company is not planning to perform an interim analysis.

Based on a review of safety data examined after approximately one-half of target enrollment was reached in the Phase 2 trial, there have been no serious adverse events related to study drug, no reports of adverse events due to hypersensitivity reactions related to study drug, and no discontinuations of study drug due to adverse events. Since CF-301 is the first lysin to be tested in humans it is important to show that it can be safety administered, thus we are encouraged by the fact that no safety issues have been reported thus far. ContraFect previously conducted a Phase 1 clinical trial of CF-301 in healthy volunteers, with no adverse safety signals reported, and the encouraging safety data from the Phase 2 trial adds to our confidence in the ability of CF-301 to be used safely to treat patients.

The Data Safety Monitoring Board (DSMB) has recommended that patients with moderate to severe renal insufficiency be administered 0.12 mg/kg CF-301 instead of 0.25 mg/kg such that those patients attain the target pharmacokinetic exposure. This recommendation was not made due to any observed safety concerns.

Financial Update

On May 10, 2018, ContraFect reported financial results for the first quarter of 2018. As expected, the company did not report any revenues for the quarter. Net loss for the first quarter of 2018 was $19.1 million, or $0.26 per share, compared to a net loss of $6.3 million, or $0.15 per share in the first quarter of 2017. The majority of this net loss was due to a $12.2 million non-cash expense due to the change in fair value of warrant liabilities. R&D expenses for the first quarter of 2018 were $4.7 million compared to $4.2 million for the first quarter of 2017. The increase was primarily due to increased spending on the Phase 2 clinical trial of CF-301. G&A expenses in the first quarter of 2018 were $2.2 million compared to $2.1 million in the first quarter of 2017. The increase was due to increased professional services and financial filing fees.

As of March 31, 2018, ContraFect had approximately $39.9 million in cash, cash equivalents, and marketable securities. We anticipate this being sufficient to fund operations through the second quarter of 2019. As of May 7, 2018, the company had approximately 73.7 million common shares outstanding and when factoring in stock options and warrants a fully diluted share count of approximately 116.1 million.

Conclusion

The data presented at ECCMID gives us further confidence in the ability of CF-301 to treat S. aureus infections (including those caused by MRSA) and we are looking forward to seeing the data from the Phase 2 study in the fourth quarter of 2018. Our valuation currently stands at $7 and given the wide disparity between our valuation and the current stock price we believe investors would be well served to take a closer look at the company in the lead up to the Phase 2 data.

PROJECTED FINANCIALS

ContraFect Corp.	2017 A	Q1 A	Q2 E	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	$4.8	$4.8	$4.9	$19.2	$19.5	$20.0
General & Administrative	$9.2	$2.2	$2.4	$2.4	$2.4	$9.4	$10.0	$10.5
Other Expenses	$0	$0	$0	$0	$0	$0	$0	$0
Operating Income	($26.6)	($7.0)	($7.2)	($7.2)	($7.3)	($28.7)	($29.5)	($30.5)
Operating Margin		-	-	-	-			
Non-Operating Expenses (Net)	$11.0	($12.1)	$0.0	$0.0	$0.0	($12.1)	($0.4)	($0.4)
Pre-Tax Income	($15.5)	($19.1)	($7.2)	($7.2)	($7.3)	($40.8)	($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)**	**($7.2)**	**($7.2)**	**($7.3)**	**($40.8)**	**($29.9)**	**($30.9)**
Net Margin		-	-	-	-			
Reported EPS	**($0.28)**	**($0.26)**	**($0.10)**	**($0.10)**	**($0.10)**	**($0.51)**	**($0.36)**	**($0.37)**
YOY Growth		-	-	-	-			
Basic Shares Outstanding	55.6	73.7	74.3	74.4	76.0	80.0	82.0	84.0

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

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