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ContraFect Corp. (CFRX-NASDAQ)

CFRX: Developing Gram-Negative Lysin Targeting* P. aeruginosa*…

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 (06/18/18)	$2.34
Valuation	**$7.00**

OUTLOOK

In Jun 2018, ContraFect Corp. (CFRX) presented multiple posters at the American Society for Microbiology (ASM) Microbe 2018 Meeting. Included in the presentations were initial *in vitro* proof-of-concept data on lead discovery Gram-negative lysins that target *Pseudomonas aeruginosa*. In addition, data was presented on *in vivo*, *in vitro*, and surveillance studies for CF-301.

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	**$2.34**
52-Week Low	**$0.88**
One-Year Return (%)	**103.48**
Beta	**-0.43**
Average Daily Volume (sh)	**103,381**
Shares Outstanding (mil)	**74**
Market Capitalization ($mil)	**$172**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**59**
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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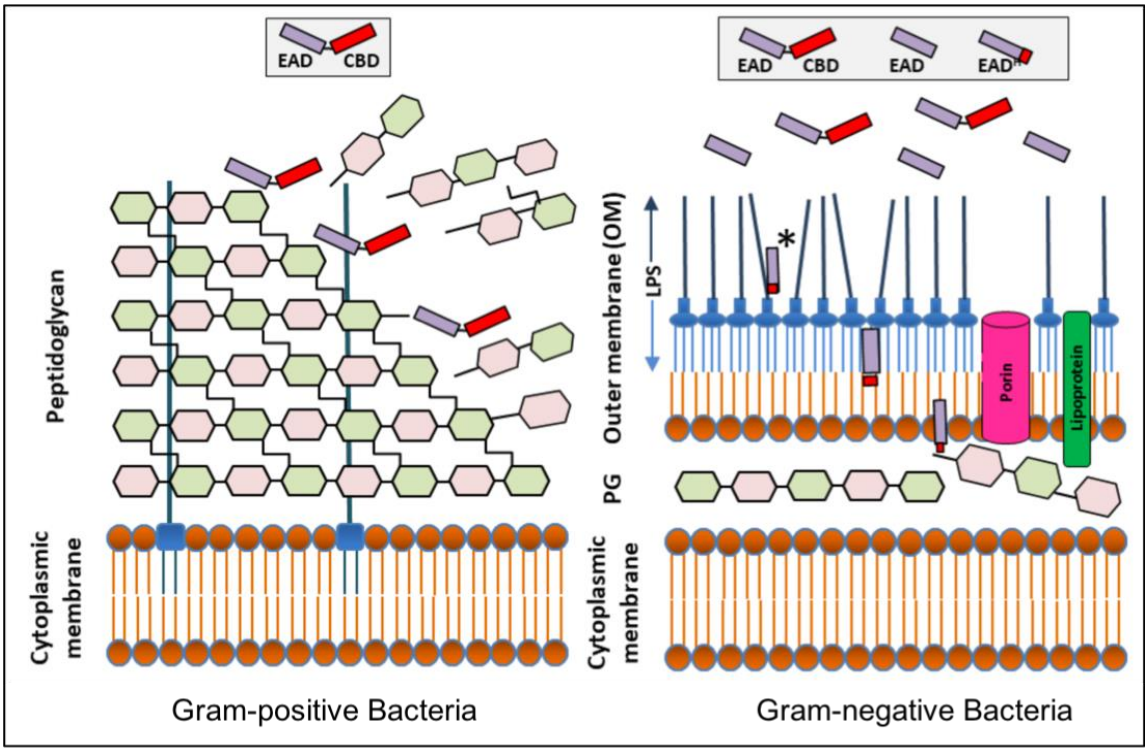
Business Update

Presentations at ASM 2018 Highlight New Gram-Negative Lysin Program and CF-301

In June 2018, ContraFect Corp. (CFRX) had multiple presentations at the American Society for Microbiology (ASM) Microbe 2018 on the company's lead drug candidate CF-301 and the Gram-negative lysin discovery program. A summary of each of the poster's is presented below.

Bacteriophage-Derived Lysins can be Engineered to Exert a Rapid and Potent Bactericidal Effect Against *Pseudomonas aeruginosa* in Serum

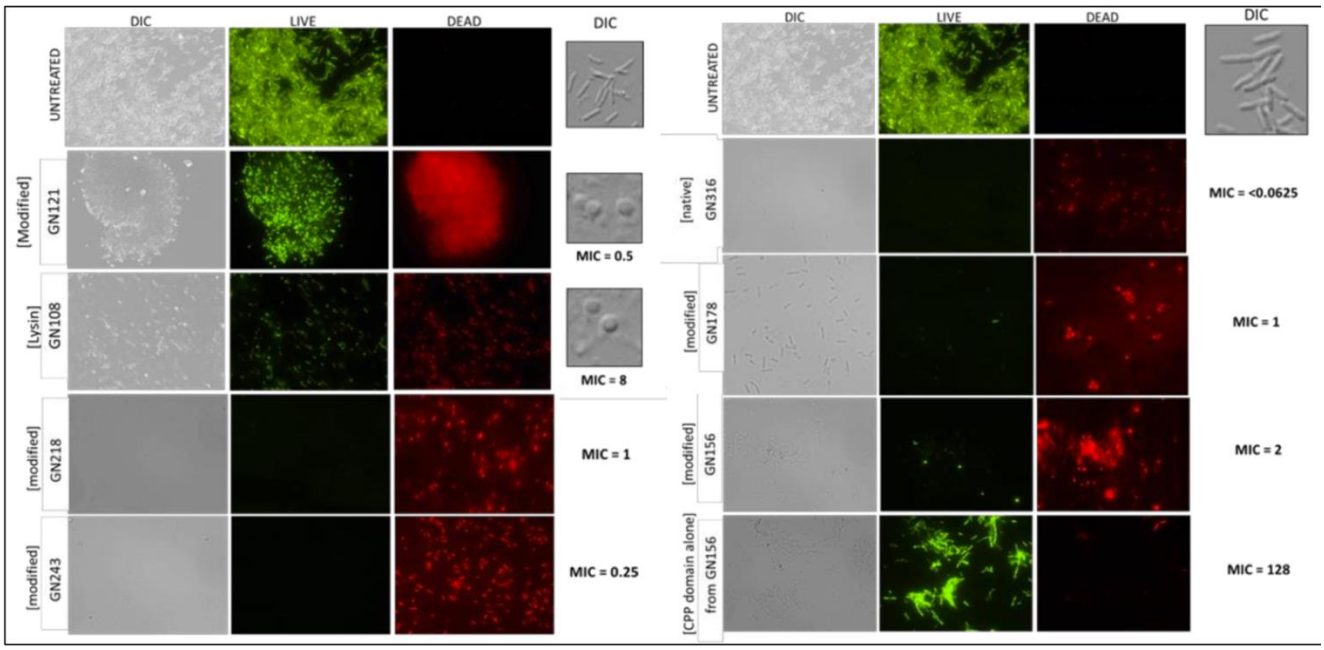
This study was undertaken as part of ContraFect's Gram-negative lysin discovery program. Gram-negative (GN) bacteria are responsible for a number of different bacterial infections and the emergence of antibiotic resistant strains is leading to a potential public health crisis. Lysins represent a novel means to treat these infections through their ability to cleave peptidoglycan bonds (peptidoglycan is the main structural component of bacterial cell walls), however their use against GN pathogens has been hindered by their inability to penetrate the outer membrane. The following figure shows how lysins are effective against Gram-positive bacteria due to their ability to easily interact with the peptidoglycan layer. However, Gram-negative bacteria have an outer membrane that acts as a barrier against most lysins, thus preventing them from reaching the peptidoglycan layer. While the majority of purified GN lysins have no antimicrobial activity, there are a select few that have some activity in low ionic strength buffers (indicated by the asterisk in the following figure on the right). It is these lysins that ContraFect used as lead compounds to modify in order to increase their anti-microbial activity in human serum.



Adapted From: Sauve *et al.*, 2018

Following screening of naturally occurring GN lysins for anti-microbial activity and targeted sequence modifications, lead lysins were tested in a variety of assays including minimum inhibitory concentration (MIC) determination, anti-biofilm activity, synergistic assays with antibiotics, and hemolysis assays. Lead

lysins exhibited MIC values between 0.06 and 16 μg/mL, anti-biofilm activity that was below the MIC value, were synergistic with a broad range of antibiotics, and did not demonstrate any hemolytic activity. An *in vitro* screening assay was then performed to determine which of those lead lysins had rapid bactericidal activity. The following show examples of lead lysins in a bactericidal activity assay after incubation with *P. aeruginosa* for 15 minutes in 100% human sera.



Source: Sauve *et al*., 2018

The most important takeaway from these studies is that it is possible to engineer lysins with rapid bactericidal activity against GN pathogens, which greatly broadens the use of lysins and could greatly expand ContraFect's pipeline. We look forward to learning more about the company's GN pipeline and selection of lead development lysins for use against *P. aeruginosa* as well as what specific indications the company will be pursuing.

Lysin CF-301 (exebacase) Administered in Addition to Vancomycin (VAN) Suppresses the Emergence of Reduced Susceptibilities to VAN Within Cardiac Vegetations in a Rabbit Model of MRSA Infective Endocarditis (IE)

This study was performed to test whether treating animals with IE with CF-301 had any effect on the development of resistance to VAN. Rabbits with IE were treated with 1) VAN alone; 2) CF-301 alone; 3) VAN + CF-301; or 4) vehicle control. Vegetations (microbial growth) were isolated from rabbits with IE and tested for resistance to VAN, CF-301, and oxacillin. MIC values against oxacillin were determined based on previous data showing that treatment with CF-301 resulted in decreased oxacillin MICs.

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 MICs. 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 32 isolates tested from rabbits treated with 1.4 μg/kg CF-301. In addition, CF-301 suppressed any increase in VAN MIC (red box) and caused an increase in susceptibility to oxacillin treatment in certain isolates (gray boxes).

Treatment Groups[a]	Log_{10} CFU/g of Vegetation[b]	n[c]	CF-301 MIC (µg/mL)[d]					VAN MIC (µg/mL)[e]				OXA MIC (µg/mL)[f]						
			0.25	0.5	1	2	4	0.5	1	2	4	<2	4	8	16	32	64	128
Pre-Treatment Control	5.46±1.78	41			41				41							5	36	
Buffer Treatment Control	7.26±1.54	32			31	1			32					2		25	5	
VAN (7.5)	6.17±2.42	32			31	1			28	4						16	16	
CF-301 (1.4)	8.24±0.02	24			24				24			7				7	10	
CF-301 (0.7)	7.93±0.12	24		1	23				24						1		23	
CF-301 (0.35)	8.17±0.58	24		3	21				24			6				7	11	
CF-301 (0.18)	8.65±0.58	16			16				16								16	
CF-301 (2.8) VAN (7.5)	<LOD																	
CF-301 (1.4) VAN (7.5)	2.92±1.73	12			12				12								12	
CF-301 (0.7) VAN (7.5)	4.23±2.92	24			24				24							10	14	
CF-301 (0.35) VAN (7.5)	3.34±0.91	34			34				34							10	24	

[a]Number in parenthesis represents dose in mg/kg
[b]LOD = limit of detection
[c]Number of isolates analyzed in MIC assays in each group
[d]The CF-301 MIC of *S. aureus* strain MW2 is 1 µg/mL
[e]The VAN MIC of *S. aureus* strain MW2 is 1 µg/mL
[f]The OXA MIC of *S. aureus* strain MW2 is 64 µg/mL

No decreased susceptibility to CF-301

CF-301 suppressed VAN MIC shift

CF-301 exposure resulted in decreased OXA MICs

Source: Oh *et al.*, 2018

Similar results were seen for isolates plated on the selective growth plates, although there were a few more isolates with a modest increase in MIC (≤ 2-fold increase). Some isolates showed increased susceptibility to oxacillin (gray boxes), which was similar to what was seen in the same assay performed with CF-301 and daptomycin.

Treatment Groups[a]	Log10 CFU/g of Vegetation[b]					n[c]	CF-301 MIC (µg/mL)[d]					VAN MIC (µg/mL)[e]				OXA MIC (µg/mL)[f]						
	0	16	32	64	128		0.25	0.5	1	2	4	0.5	1	2	4	<2	4	8	16	32	64	128
Pre-Treatment Control	5.46±1.78	4.33±1.75	3.91±1.48	2.53±0.31	<LOD	35			35				35							12	23	
Buffer Treatment Control	7.26±1.54	3.37±1.13	4.95±1.81	3.19±1.61	<LOD	44			44				44							35	9	
VAN (7.5)	6.17±2.42	4.85±1.88	4.41±1.71	3.82±1.37	<LOD	40			38	2			39	1						17	23	
CF-301 (1.4)	8.24±0.02	7.1±0.06	5.97±0.03	4.23±1.74	<LOD	24			20	4			24			3				8	13	
CF-301 (0.7)	7.93±0.12	6.7±0.14	5.78±1.09	3.81±1.84	<LOD	24		2	19	3			24						3	1	20	
CF-301 (0.35)	8.17±0.58	6.96±0.21	6.42±0.49	5.5±0.62	3.4±1.33	24			22	2			24			7					17	
CF-301 (2.8) VAN (7.5)	<LOD	<LOD	<LOD	<LOD	<LOD																	
CF-301 (1.4) VAN (7.5)	2.92±1.73	2.51±1.06	2.46±0.9	2.35±0.57	<LOD	12			12				12							1	11	
CF-301 (0.7) VAN (7.5)	4.23±2.92	3.78±2.16	3.73±2.10	2.86±1.31	<LOD	17			17				17							8	9	
CF-301 (0.35) VAN (7.5)	3.34±0.91	3.41±1.04	2.92±0.66	<LOD	<LOD	14			14				14								14	

[a]Number in parenthesis represents dose in mg/kg
[b]LOD = limit of detection
[c]Number of isolates analyzed in MIC assays in each group
[d]The CF-301 MIC of *S. aureus* strain MW2 is 1 µg/mL
[e]The VAN MIC of *S. aureus* strain MW2 is 1 µg/mL
[f]The OXA MIC of *S. aureus* strain MW2 is 64 µg/mL

≤2-fold shift increase

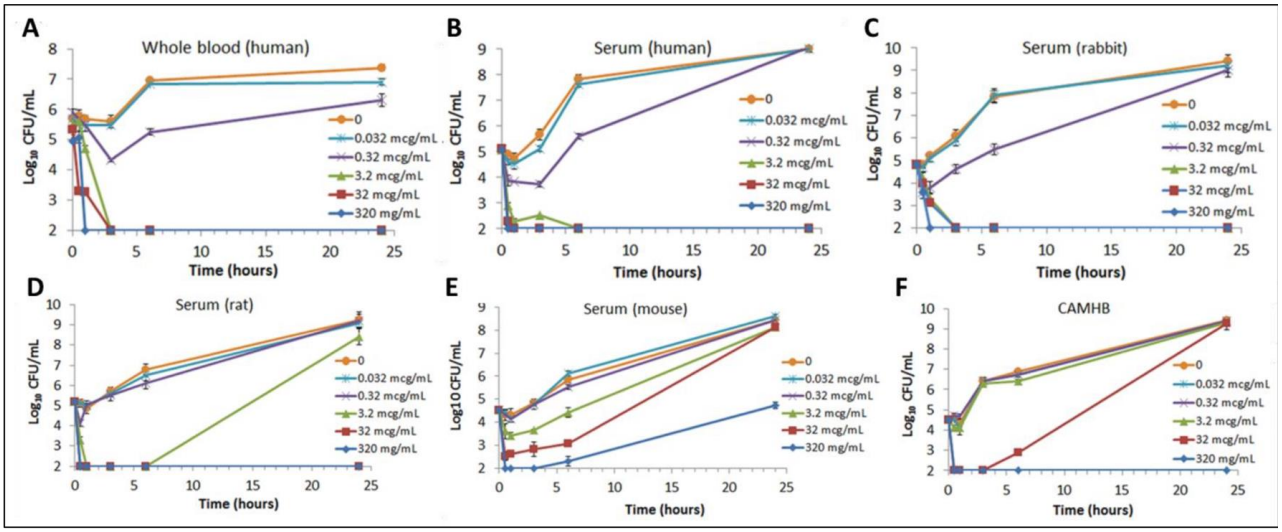
CF-301 exposure resulted in decreased OXA MICs

Source: Oh *et al.*, 2018

The most important conclusion from this study is that while a modest increase in CF-301 MIC was observed, based on PK modeling 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.

Lysin CF-301 (exebacase) Activates Latent Host Factors in Human Blood to Potentiate Bacteriolysis

The purpose of this study was to test the activity of CF-301 in various mammalian and rodent blood matrices compared to cation-supplemented Mueller Hinton Broth (caMHB). A wide variance in activity was discovered between the different blood matrices and caMHB. CF-301 MICs observed in rabbit, dog, horse, and human blood matrices were up to 64-fold lower compared to MICs obtained in rat and mouse blood. The following graphs show that minimum sterilizing concentrations for CF-301 in human blood was 3.2 µg/mL, 32 µg/mL for rat blood, and ≥ 320 µg/mL in mouse blood. These results were seen when testing 10 different staphylococcal strains and in blood from multiple pooled individuals and polled sources.



Source: Indiani *et al.*, 2018

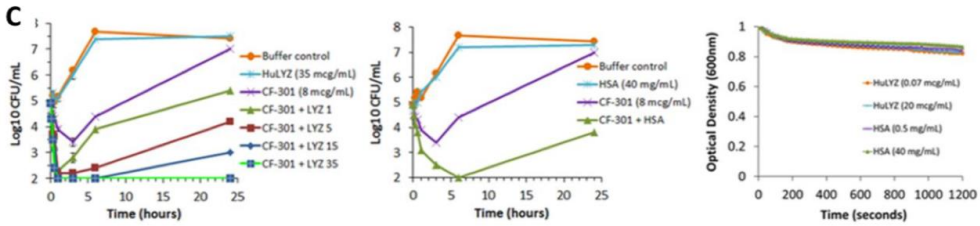
These results led to the hypothesis that CF-301 synergizes with some component(s) or activates latent anti-staphylococcal activity in the blood. To test this, CF-301 was tested with a wide range of serum proteins in caMHB. The following chart shows that human lysozyme (HuLYZ) and albumin (HSA) were identified in checkerboards (A), lytic assay (B), and time-kill assays (C).

A

Agent	Description	ΣFIC_{min}	Interaction
Lysozyme	Human, recombinant	≤0.05	Synergy
Lysozyme	Hen egg-white	≤0.563	Additive
Lysozyme	Human neutrophil derived	≤0.056	Synergy
Serum albumin	Human, fraction V	≤0.086	Synergy
Serum albumin	Human, recombinant	≤0.1	Synergy
Serum albumin	Rabbit, from serum	≤0.1	Synergy

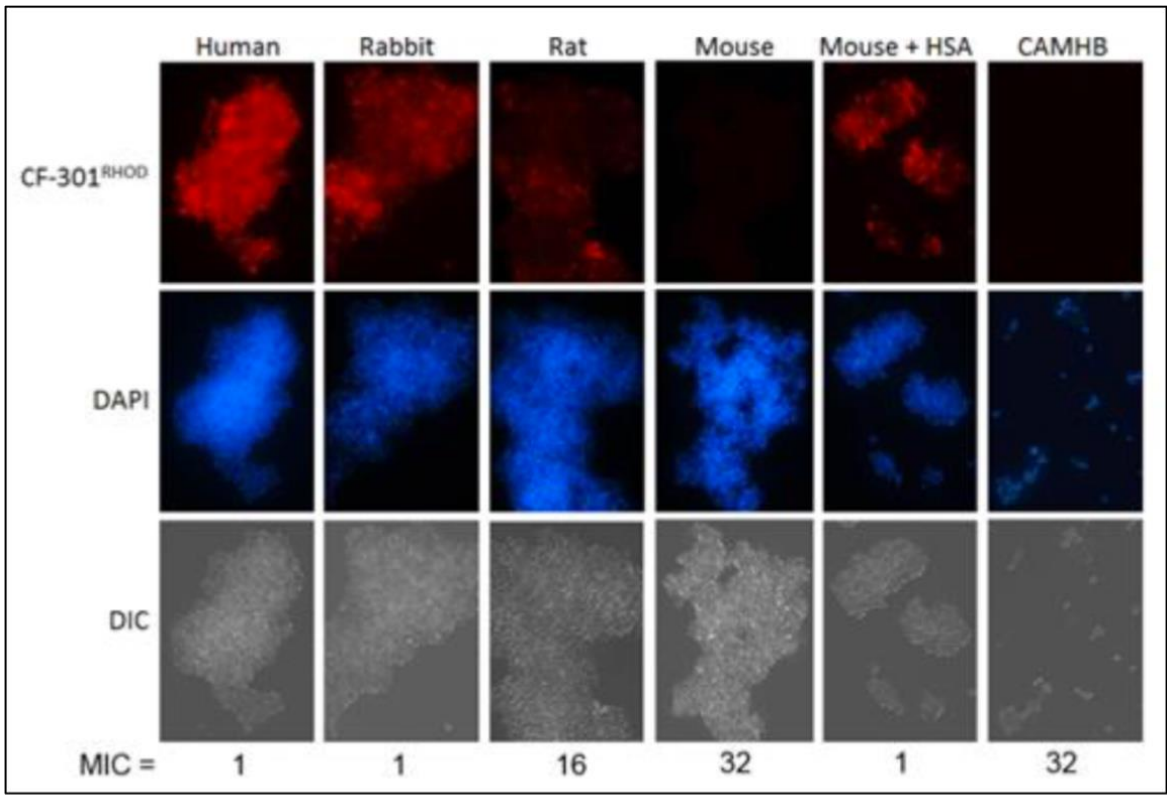
B

Supplement (concentration)	Specific activity (Units/mg)	Fold increase in specific activity
None	2419	n.a.
HSA (40 mg/mL)	43067	17.8
HuLYZ (10 µg/mL)	23706	9.8
HSA + HuLYZ	60475	25.0



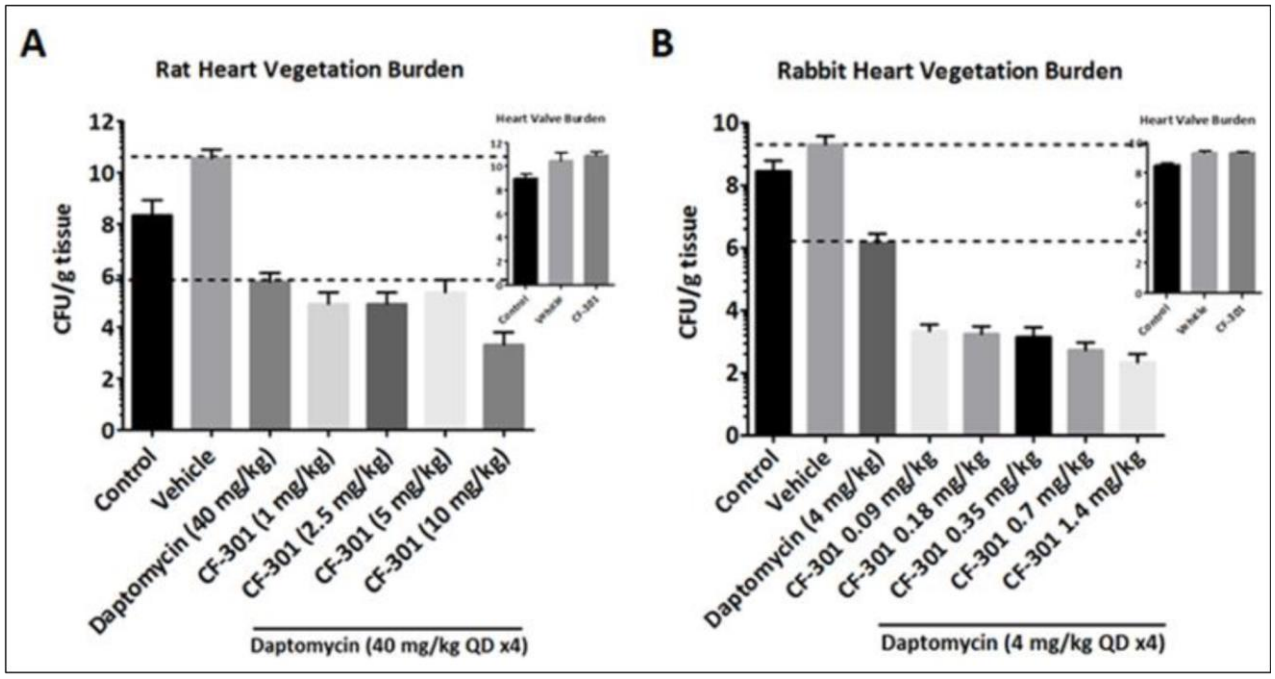
Source: Indiani *et al.*, 2018

The mechanism by which this enhancement occurred was investigated and found to be due to the accumulation of CF-301 at the surface of *S. aureus* cells based on its interactions with HSA and facilitation of HuLYZ activity. The following image shows much greater binding of CF-301 to *S. aureus* cells (depicted by red color) in human and rabbit blood compared to rat or mouse blood.



Source: Indiani *et al*., 2018

These *in vitro* results were confirmed by an *in vivo* test performed in rabbit and rat IE models. The following graphs show that a >50-fold higher dose of CF-301 was required for similar efficacy in the rat model (10 mg/kg) compared to the rabbit model (0.09 mg/kg).



Source: Indiani *et al*., 2018

The results of these studies show that CF-301 has differentiated characteristics compared to small molecule antibiotics in that binding to albumin increases activity of the enzyme, while binding of small molecule antibiotics to albumin typically decreases their activity. In addition, it reaffirms the company's use of 0.25 mg/kg dose in the Phase 2 study.

Lysin CF-301 (exebacase) Demonstrates Potent *in vitro* Activity Against a Range of Staphylococcus and Streptococcus Species Associated with Complicated Bacteremia and Infective Endocarditis (IE) in Humans

This experiment was performed to determine which species of staphylococcal and streptococcal bacteria known to cause IE are susceptible to CF-301. MIC values for CF-301, vancomycin (VAN), and daptomycin (DAP) were determined against a total of six staphylococcal and 13 streptococcal species. The following two tables show the MIC values for CF-301 against the tested strains. Importantly, all of the staphylococcal strains tested were susceptible with MIC values for CF-301 of 1-2 μg/mL.

Results: MICs for *Staphylococcus* spp.

Organism	N	CF-301 MIC (μg/mL)			DAP MIC (μg/mL)			VAN MIC (μg/mL)		
		MIC_{50}	MIC_{90}	Range	MIC_{50}	MIC_{90}	Range	MIC_{50}	MIC_{90}	Range
S. aureus (MRSA)	315	0.5	1	0.12-1	0.5	0.5	0.06-1	1	1	0.5-2
S. aureus (MSSA)	310	0.5	1	0.25-1	0.5	0.5	0.25-1	1	1	0.5-2
S. epidermidis	54	0.5	0.5	0.12-2	0.5	0.5	0.12-1	1	2	1-2
S. capitis	5	0.25	1	0.25-4	0.5	1	0.25-1	0.5	1	0.5-1
S. haemolyticus	22	1	2	0.25-2	0.5	1	0.25-2	2	2	0.5-4
S. lugdunensis	23	0.5	1	0.25-2	0.5	0.5	0.25-0.5	1	1	0.5-1
S. warneri	19	0.5	1	0.06-1	0.5	1	0.25-2	1	2	0.25-2

Source: Watson *et al.*, 2018

MIC values for CF-301 were higher for most of the streptococcus species, although *S. intermedius*, *S. dysgalactiae*, *S. pyogenes* and *S. agalactiae* were all susceptible (MIC = 0.5, 2, 2, and 2 μg/mL, respectively).

Results: MICs for *Streptococcus* spp.

Organism	N	CF-301 MIC (μg/mL)			DAP MIC (μg/mL)			VAN MIC (μg/mL)		
		MIC_{50}	MIC_{90}	Range	MIC_{50}	MIC_{90}	Range	MIC_{50}	MIC_{90}	Range
S. pyogenes (Group A)	102	1	2	0.5-4	0.12	0.5	0.015-0.5	0.25	0.5	0.25-0.5
S. agalactiae (Group B)	101	1	2	0.25-4	0.09	0.12	0.015-0.25	0.5	0.5	0.5-2
S. anginosus	14	32	64	1-64	0.5	0.5	0.25-0.5	0.5	1	0.5-1
S. dysgalactiae	24	1	2	1-32	0.12	0.5	0.062-0.5	0.5	0.5	0.25-1
S. gallolyticus	23	64	>512	0.25->512	0.12	0.25	0.06-0.5	0.25	0.5	0.25-0.5
S. gordonii	12	4	8	0.5-8	0.5	1	0.25-1	0.5	1	0.5-1
S. intermedius	10	0.25	0.5	0.25-0.5	0.5	1	0.12-0.5	1	1	1
S. mitis	21	2	64	0.5-64	0.5	1	0.12-1	0.5	0.5	0.25-0.5
S. mutans	23	32	>64	1->64	0.5	1	0.25-8	1	1	0.25-1
S. oralis	15	4	64	0.5-64	0.5	1	0.5-1	0.5	1	0.5-1
S. salivarius	15	2	8	0.5-8	0.25	0.5	0.06-0.5	0.5	0.5	0.25-0.5
S. sanguinis	17	4	16	2-32	0.25	1	0.06-1	0.5	0.5	0.5

Source: Watson *et al.*, 2018

The important take away from this study was that CF-301 is active against a wide range of staphylococcal species, and some streptococcal species, and may have the potential to treat IE caused by these species.

CF-301 (Exebacase) Activity versus Contemporary *Staphylococcus aureus* Clinical Isolates from Six US Hospitals

This study was undertaken to determine the effectiveness of CF-301 against *S. aureus* clinical isolates collected in the U.S. A total of 300 samples were tested that included both methicillin-sensitive (MSSA, n = 150) and methicillin-resistant (MRSA, n=150) *S. aureus*, thus they represent a “real-world” test of CF-301 activity. The following table shows the number of isolates that were inhibited by various concentrations of CF-301. This data is in agreement with a clinical isolate study from 2011 performed in

the U.S. and a recently reported clinical isolate study from European hospitals. Importantly, none of the isolates had a MIC value higher than 1 μg/mL, which is expected to correspond to susceptibility to the clinical dose of 0.25 mg/kg being used in the Phase 2 study.

S. aureus (no. of isolates)	Year	Number of isolates inhibited by CF-301 MIC (μg/mL) of:						MIC_{50} (μg/mL)	MIC_{90} (μg/mL)
		0.125	0.25	0.5	1	2	4		
MSSA (150)	2016-2017		2	91	57			0.5	1
MRSA (150)	2016-2017		5	108	37			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 in patients with bacteremia, including those with endocarditis, which is caused by both methicillin-resistant (MRSA) and methicillin-sensitive (MSSA) strains of *S. 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.

Conclusion

The Gram-negative lysin program is an exciting opportunity for the company and the data that has been compiled thus far for the development candidates is very encouraging. We look forward to getting updates on this program as it progresses.

The data presented at ASM for CF-301 gives us further confidence in its ability 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. We believe interest in ContraFect and the lysin story will begin to increase as we get closer to the data readout. For example, Reuters recently had a report on lysins that featured ContraFect CMO Dr. Cara Cassino, which can be viewed here. 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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