Zacks Small-Cap Research

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ContraFect Corp

(CFRX-NASDAQ)

CFRX: Sufficient Capital To Fund Company Past Phase 2 Results for CF-301…

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 (08/14/17)	$1.25
Valuation	**$7.00**

OUTLOOK

On August 9, 2017, ContraFect Corp. (CFRX) announced financial results for the second quarter of 2017. The company exited the quarter with approximately $21.7 million in cash, cash equivalents, and marketable securities. In July 2017, ContraFect completed a $36.9 million underwritten public offering that will fund operations into the first half of 2019.

During the second quarter of 2017, ContraFect initiated a Phase 2 clinical trial of CF-301 in patients with bacteremia caused by *Staphylococcus aureus*. We anticipate results in the fourth quarter of 2018.

SUMMARY DATA

52-Week High	**$3.10**
52-Week Low	**$1.10**
One-Year Return (%)	**-45.41**
Beta	**-0.89**
Average Daily Volume (sh)	**164,172**
Shares Outstanding (mil)	**74**
Market Capitalization ($mil)	**$92**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**25**
Insider Ownership (%)	**9**
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 2016 Estimate	**N/A**
P/E using 2017 Estimate	**N/A**

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)
2016	0 A	0 A	0 A	0 A	0 A
2017	0 A	0 A	0 E	0 E	0 E
2018					0 E
2019					0 E

Earnings per Share
(EPS is operating earnings before non recurring items)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2016	-$0.32 A	-$0.35 A	-$0.28 A	$0.01 A	-$0.85 A
2017	-$0.15 A	-$0.07 A	-$0.11 E	-$0.10 E	-$0.43 E
2018					-$0.41 E
2019					-$0.48 E

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WHAT'S NEW

Financial Update

On August 9, 2017, ContraFect Corp. (CFRX) announced financial results for the second quarter of 2017. As expected, the company did not report any revenues. The net loss for the quarter was $2.8 million, or $0.07 per share, and consisted of $3.8 million in R&D expenses and $2.3 million in G&A expenses. R&D expenses for the quarter were decrease by $3.5 million compared to the same time period in 2016 as a result of a decrease in spending on CF-404 cGMP manufacturing and external preclinical and non-clinical studies. G&A expenses were decreased by $0.2 million compared to the same time period in 2016 as a result of a decrease in legal expenses. Other income was $3.2 million for the second quarter of 2017, compared with $0.1 million for the second quarter of 2016. The increase relates to a non-cash gain resulting from the change in fair value of the company's warrant liabilities.

Total cash burn for the quarter was approximately $7.0 million, and the company had approximately $21.7 million in cash, cash equivalents, and marketable securities as of Jun. 30, 2017. In July 2017, the company completed an underwritten public offering of 32 million shares of common stock along with warrants to purchase 16 million shares of common stock at an exercise price of $1.55. The public offering price was $1.25 per share of common stock and accompanying warrant, which resulted in net proceeds to the company of approximately $36.9 million. We believe this will be sufficient to fund operations into the first half of 2019, thus the company should be fully funded through the end of the Phase 2 trial of CF-301, with results from that trial expected in the fourth quarter of 2018.

As of August 8, 2017, the company had approximately 73.7 million shares outstanding. In addition, there are approximately 6.0 million stock options and 36.3 million warrants for a fully diluted share count of approximately 116.0 million. The company recently increased the number of authorized shares from 100 million to 200 million.

Business Update

CF-301

ContraFect's lead lysin product is CF-301. A lysin is a naturally occurring anti-bacterial hydrolytic enzyme that is produced by bacteriophages, which are virus' that infect and kill bacteria. Lysins are highly evolved enzymes that are able to target one of the five bonds in peptidoglycan (murein), the main component of bacterial cell walls. A typical lysin, such as CF-301, comprises two domains separated by a short linker region. The N-terminal domain catalyzes the hydrolysis of peptidoglycan whereas the C-terminal domain binds to the cell wall substrate, often a carbohydrate, which confers a great specificity and decreases the chance for bacterial resistance. Due to this, the use of lysins as antibacterial agents is designed to combat drug resistance to currently used antibiotics.

CF-301 will initially be targeted for the treatment of bacteremia, or infections of the bloodstream. Most studies estimate the incidence of *S. aureus* bacteremia (SAB) ranging from 20-50 cases/100,000 population (Klevens *et al*., 2007; Benfield *et al*., 2006; El Atrouni *et al*., 2009). Prior to the advent of antibiotics, the mortality rate from SAB was close to 80% (Mendell, 1939). The introduction of antibiotics, coupled with greater standards of care, has reduced the mortality rate, which appears to have stabilized at approximately 20% (Turnidge *et al*., 2009). SAB can frequently lead to infective endocarditis (IE), an infection of the endocardial surface of the heart (Fowler *et al*., 2005). The prevalence of IE is estimated to be anywhere from 11 to 50% of patients with SAB. Development of IE leads to an increased risk of embolic event and death (Miro *et al*., 2005).

Due to widespread resistance to penicillin, the current treatment of choice for *S. aureus* infections is semi-synthetic penicillin molecules. This resistance is due to the activity of the enzyme penicillinase, which cleaves the β-lactam ring of the penicillin molecule. Penicillinase-resistant β-lactam antibiotics include methicillin, oxacillin, and flucoxacillin. *S. aureus* strains that have acquired resistance to methicillin have an altered penicillin-binding protein (PBP2a) that has lower affinity for binding β-lactam antibiotics, thus rendering them ineffective. Strains that have acquired this resistance are referred to as methicillin-resistant *S. aureus* (MRSA). The current gold standard for treatment of MRSA is vancomycin. However, vancomycin is far from ideal due to poor tissue penetration, slow bactericidal activity, and a number of side effects (Gould, 2008). Additional antibiotics utilized include teicoplanin, tegecyline, linezolid, daptomycin, and televancin. Each of those medications has their own shortcomings, including the development of resistance, thus there exists a significant unmet medical need for newer therapies, particularly

those that are not susceptible to the development of resistance. Pre-clinical data shows that CF-301 synergizes with standard-of-care antibiotics, which results in a very high survival rate in mouse models of bacteremia.

Phase 2 Clinical Trial

The company has initiated a Phase 2 clinical trial of CF-301 in patients with bacteremia, including those with endocarditis, which is caused by both MRSA and methiciliin-sensitive strains of *Staphylococcus aureus*. The trial is an international, multicenter, randomized, double blind, placebo controlled study with a superiority comparison between CF-301 combined with the standard of care antibiotics compared to placebo 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.

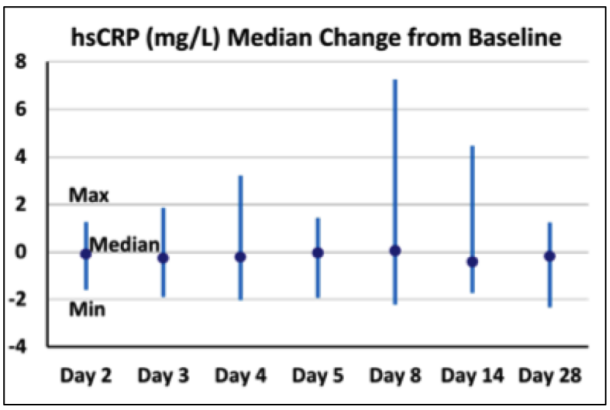
New Clinical and Microbiological Data Presented on CF-301

ContraFect recently presented five posters at the American Society for Microbiology (ASM) Microbe 2017 conference. Initial data from the Phase 1 study of CF-301, which was released in late 2015, showed the compound to be well tolerated with no adverse safety signals. The new data further supports the safety profile of CF-301, including an absence of acute cardiovascular and inflammatory responses. In addition, the company presented data showing CF-301 has a low propensity to induce resistance and that very low concentrations of CF-301 may increase susceptibility to conventional antibiotics.

Poster #1: Inflammatory Markers in a Phase 1 Placebo Controlled Dose Escalating Study of Intravenous Doses of CF-301 in Human Subjects

Since CF-301 is a nonhuman protein, it is conceivable that dosing could elicit an inflammatory response, thus a range of inflammatory markers were evaluated before and after dosing. ContraFect analyzed high-sensitivity C-reactive protein (hs-CRP), erythrocyte sedimentation rate (ESR), and complement factors Bb, C3a, C5a, and CH50. IL-6 and TNF-α were only to be collected if a subject experienced infusion reaction symptoms, and since that did not occur those factors were not analyzed.

The data showed that outside of one subject who received CF-301 having an increase in hsCRP on Day 8 following infusion (with no associated clinical symptoms), there was little to no change in hsCRP for those who received CF-301, with similar changes seen in the placebo group.



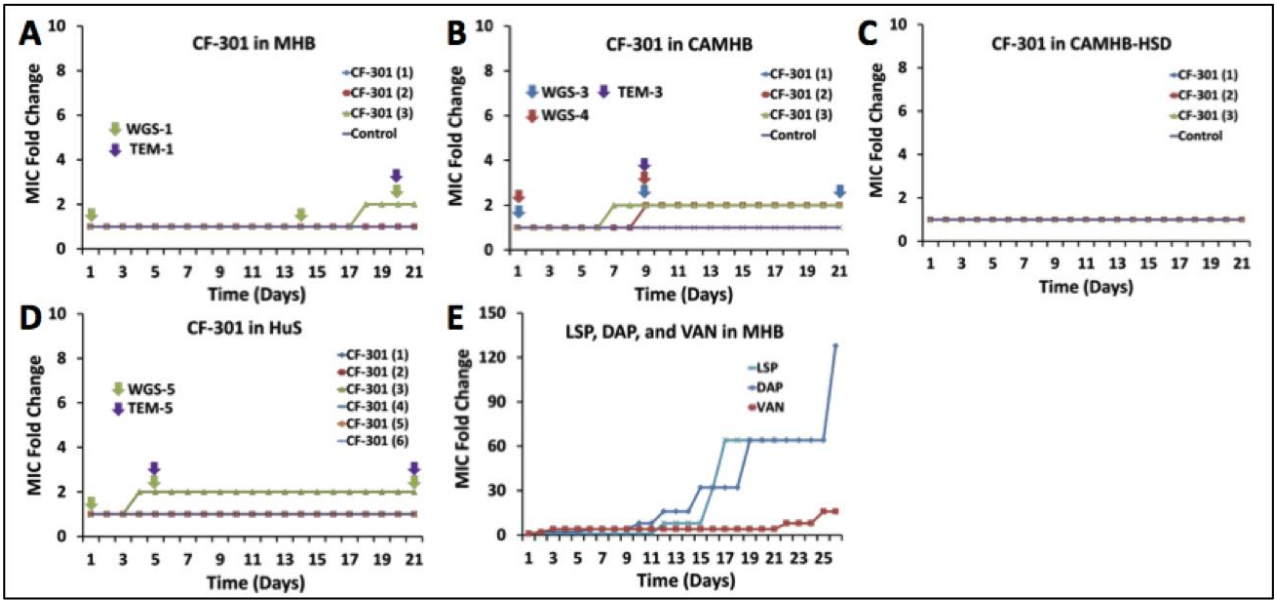
Source: Jandourek *et al.*, 2017

There were also no differences between placebo and CF-301 treated subjects for any of the other factors evaluated. The results suggest that there is a low propensity for a single dose of CF-301 to induce an inflammatory response.

Poster #2: Low Propensity of Resistance Development In Vitro in Staphylococcus aureus with Lysin CF-301

ContraFect had previously performed a serial passage study using the methicillin-resistant *Staphylococcus aureus* (MRSA) strain MW2. Those results showed a 2-fold increase in the minimum inhibitory concentration (MIC), however this never increased beyond 2-fold.

As a follow up, additional serial passage studies were performed using both MW2 and the methicillin-sensitive *S. aureus* (MSSA) strain ATCC 29213 in different types of media along with human serum. The following graphs show that the CF-301 MIC never increased more than 2-fold in any type of media or human serum, while comparator agents demonstrated high-level resistance (up to 128-fold; graph E)



Source: Oh *et al.*, 2017

Even with a 2-fold increase in MIC, those variants will remain susceptible to the clinical dose of 0.25 mg/kg based on exposure attainment studies and pharmacokinetic modeling. Importantly, these results suggest that the propensity for CF-301 resistance in *S. aureus* is low.

Poster #3: The Sub-MIC Effect of CF-301 on *Staphylococcus aureus*

ContraFect had previously performed a series of experiments demonstrating a strong post-antibiotic effect, post-antibiotic sub-MIC effect, and sub-MIC effect of CF-301 on a panel of 14 staphylococcal strains. This poster presented data that more thoroughly examined the CF-301 sub-MIC effect on structure, antibiotic susceptibility, biofilm formation, *in vitro* growth, and proliferation in a murine infection model.

The following tables show that treatment of MW2 with sub-MIC concentrations of CF-301 decreases the MIC for daptomycin, and vice versa. This is important as ContraFect is testing CF-301 with standard of care antibiotics, thus the ability of CF-301 to increase antibiotic susceptibility may lead to more favorable clinical outcomes.

SME induced with CF-301

[CF-301] (xMIC)	Fold reduction (DAP MIC)
0.5	>8
0.25	>8
0.125	8
0.06	4
0.03	4
0.015	2
0.008	2

SME induced with DAP

SME induction (xMIC DAP)	Fold reduction (CF-301 MIC)
0.75	8
0.4	4
0.2	4
0.1	4
0.05	4
0.025	2
0.013	2

Source: Oh *et al.*, 2017

Conclusion and Valuation

The data recently presented by ContraFect helps to further establish the safety of CF-301 and its ability to increase susceptibility of *S. aureus* strains (including MRSA strains) to antibiotics. The company has initiated the Phase 2 study of CF-301 and we look forward to evaluating the results next year, which we anticipate in 4Q18. We have constructed a probability adjusted discounted cash flow model that takes into account potential future revenues from CF-301 and the company's influenza treatment CF-404. Our valuation currently stands at $7 per share, and we believe that all investors interested in the anti-infective space should consider taking a closer look at ContraFect.

PROJECTED INCOME STATEMENT

ContraFect Corp.
Income Statement

ContraFect Corp.	2016 A	Q1 A	Q2 A	Q3 E	Q4 E	2017 E	2018 E	2019 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	$22.1	$4.2	$3.8	$5.0	$5.1	$18.1	$20.0	$25.0
General & Administrative	$11.4	$2.1	$2.3	$2.4	$2.4	$9.3	$11.0	$13.0
Other Expenses	$0	$0	$0	$0	$0	$0	$0	$0
Operating Income	($33.5)	($6.3)	($6.1)	($7.4)	($7.5)	($27.3)	($31.0)	($38.0)
Operating Margin	-	-	-	-	-			
Non-Operating Expenses (Net)	$5.0	($0.0)	$3.2	($0.1)	($0.1)	$3.0	($0.4)	($0.4)
Pre-Tax Income	($28.5)	($6.3)	($2.8)	($7.5)	($7.6)	($24.3)	($31.4)	($38.4)
Income Taxes Paid	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	**($28.5)**	**($6.3)**	**($2.8)**	**($7.5)**	**($7.6)**	**($24.3)**	**($31.4)**	**($38.4)**
Net Margin	-	-	-	-	-			
Reported EPS	**($0.85)**	**($0.15)**	**($0.07)**	**($0.11)**	**($0.10)**	**($0.43)**	**($0.41)**	**($0.48)**
YOY Growth	-	-	-	-	-			
Basic Shares Outstanding	33.5	41.6	41.7	70.0	74.0	56.8	76.0	80.0

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

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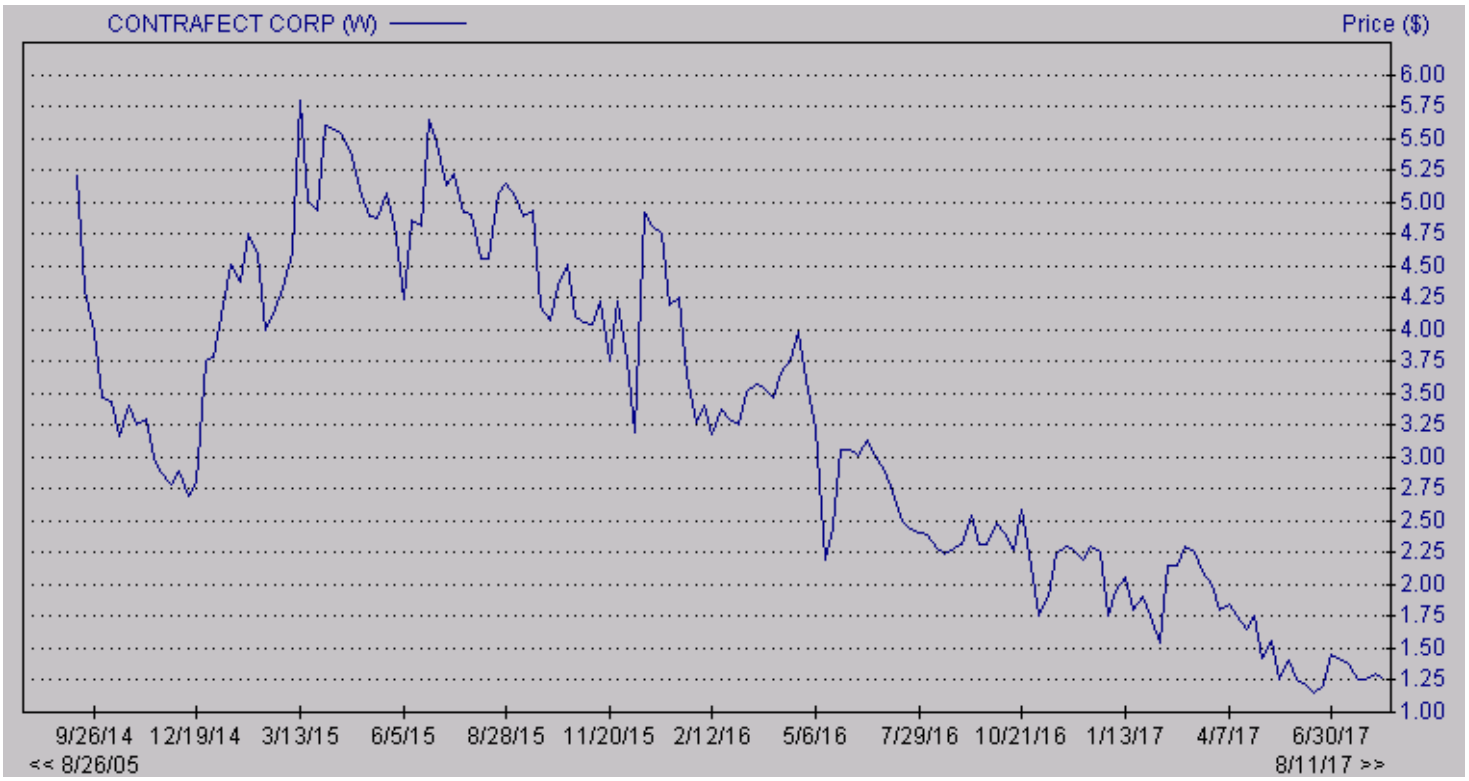
HISTORICAL STOCK PRICE



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