Zacks Small-Cap Research

May 17, 2016
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Contrafect Corp

(CFRX-NASDAQ)

CFRX: Phase 2 Trial of CF-301 in Bacteremia Patients to Commence in 4Q16…

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 $12/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 (05/17/16)	$2.50
Valuation	**$12.00**

OUTLOOK

On May 10, 2016, ContraFect Corp. announced financial results for the first quarter of 2016 and provided a business update. The company reported a net loss for the first quarter of $8.9 million, or $0.32 per share. As of Mar. 31, 2016, the company had approximately $26.3 million in cash and cash equivalents, which we believe is sufficient to fund operations into the first half of 2017.

ContraFect will be initiating a Phase 2 clinical trial of CF-301 in patients with bacteremia caused by *Staphylococcus aureus* in the fourth quarter of 2016.

SUMMARY DATA

52-Week High	**$5.86**
52-Week Low	**$2.10**
One-Year Return (%)	**-52.12**
Beta	**-0.93**
Average Daily Volume (sh)	**42,957**
Shares Outstanding (mil)	**27**
Market Capitalization ($mil)	**$65**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**18**
Insider Ownership (%)	**15**
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)
2015	0 A	0 A	0 A	0 A	0 A
2016	0 A	0 E	0 E	0 E	0 E
2017					0 E
2018					0 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2015	-$0.24 A	-$0.33 A	-$0.22 A	-$0.28 A	-$1.08 A
2016	-$0.32 A	-$0.23 E	-$0.28 E	-$0.27 E	-$1.11 E
2017					-$0.89 E
2018					-$0.92 E

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WHAT'S NEW

Financial Update

On May 10, 2016, ContraFect Corp. (CFRX) announced financial results for the first quarter of 2016. As expected, the company did not report any revenues. The net loss for the quarter was $8.9 million, or $0.32 per share, and consisted of $4.4 million in R&D expenses and $4.7 million in G&A expenses offset by a $0.2 million gain in other income. R&D expenses for the quarter were increased by $2.0 million compared to the same time period in 2015 as a result of a $1.4 million increase in expenditures on CF-301 in preparation for the Phase 2 clinical trial later in 2016, and additional IND-enabling studies for CF-404. G&A expenses were increased by $2.4 million over the same time period in 2015 as a result of $2.0 million in severance costs, and $0.5 million in non-cash share-based compensation. Total cash burn for the quarter was $6.5 million, and the company had approximately $26.3 million in cash and cash equivalents as of Mar. 31, 2016. We believe this will be sufficient to fund operations into the first half of 2017.

CF-301 Update

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).

The treatment of choice for *S. aureus* infections is penicillin, however in most countries penicillin resistance is extremely common. Resistance to penicillin 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.

Positive Results from Phase 1 Trial of CF-301

On April 9, 2016, ContraFect Corp. (CFRX) presented results from the Phase 1 clinical trial of CF-301, the company's lead lysin product, in healthy volunteers at the 26th European Congress of Clinical Microbiology and Infectious Disease (ECCMID). The trial was a randomized, double blind, placebo controlled, dose ranging Phase 1 study in healthy volunteers to determine if there were any adverse effects seen with single administrations of CF-301 at various doses, as well as to determine the pharmacokinetic parameters of the molecule (NCT02439359).

Twenty subjects were dosed (11 male/9 female; 13 active/7 placebo) amongst each of the four planned dose levels. There were no serious adverse events (AEs), no hypersensitivity reactions to CF-301, and no study stopping rules

were met. There were five non-serious AEs reported by four subjects: two subjects who received CF-301 reported headache, contact dermatitis, and allergic rhinitis while two subjects who received placebo reported viral upper respiratory tract infection and viral infection. Importantly, there were no clinically relevant changes in vital signs, EKGs, or laboratory results. The breakdown of AEs is presented in the following table.

Summary of Treatment Emergent Adverse Events (TEAE)

	CF-301 mg/kg/dose					
	0.04 (N=4)	0.12 (N=4)	0.25 (N=4)	0.4 (N=1)	Total CF-301 (N=13)	Placebo (N=7)
Total # TEAEs	1	2	0	0	3	2
# Subjects with at least one TEAE n (%)	1 (25.0)	1 (25.0)	0 (0)	0 (0)	2 (15.4)	2 (28.6)

Source: Cassino *et al.*, 2016

While the values were not given on the poster, it was reported that nine of thirteen (69%) subjects who received CF-301 generated anti-CF-301 anti-drug antibody (ADA) titers of "variable magnitude". It is not surprising that a majority of the subjects dosed with CF-301 developed antibodies to the compound since it is a foreign protein. These antibodies are unlikely to be physiologically relevant for patients receiving a single dose of CF-301, however what effect they may have on the ability to re-dose a patient will need to be examined in future clinical studies.

Perhaps most importantly in regards to immunological response, no subjects tested positive for CF-301 BAT activation and only one subject tested weakly positive for anti-CF-301 IgE at Day 28. The cutoff for positivity of anti-CF-301 IgE was >0.1 kU/L and the subject who tested positive had a value of 0.18 kU/L. The same subject then tested negative for anti-CF-301 IgE on Day 90, thus this appears as though it was a transient response. There did not appear to be a relationship between anti-CF-301 ADA and either the BAT or the IgE assays.

PK parameters showed that as the dose of CF-301 increased, C_{max} and area under the curve (AUC) increased in a dose-related but less than a dose-proportional manner, although there was no indication of a plateau in dose response. The following table gives a summary of the PK parameters from the trial.

Summary of PK Parameters for CF-301

Parameter*	0.04 mg/kg n=4	0.12 mg/kg n=4	0.25 mg/kg n=4	0.4 mg/kg n=1
C_{max} (ng/mL)	205 (14.2)	489 (16.1)	731 (25.4)	1,212
$AUC_{(0-t)}$ (hr×ng/mL)	498 (12.8)	1,121 (16.0)	1,749 (25.0)	3,311
$AUC_{(inf)}$ (hr×ng/mL)	503 (12.6)	1,126 (16.0)	1,758 (24.8)	3,316
$t_{1/2}$ (hr)	6.58 (52.6)	4.37 (6.79)	6.05 (64.9)	11.3

***Geometric mean (geometric CV)**

Source: Cassino *et al.*, 2016

In summary, results from the CF-301 Phase 1 clinical trial showed the compound to be well tolerated with no serious AEs reported. While a majority of subjects developed ADAs, these did not correlate with any hypersensitivity reactions. These results are very important for the company, as there does not appear to be any increased risk of hypersensitivity reaction through injection of a lysin. The company announced that a CF-301 dose of 0.25 mg/kg, along with standard of care antibiotics, will be utilized in the upcoming Phase 2 study. The results

from the Phase 1 study give us confidence that there will not be any safety-related issues with this dose level in future clinical trials.

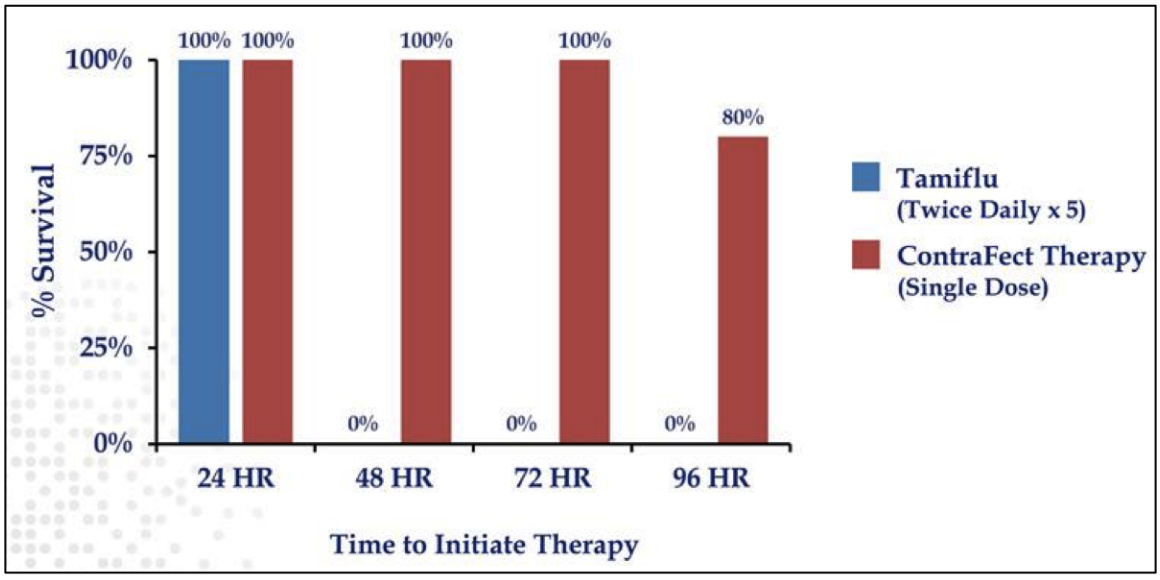
Next Steps in Development of CF-301

The company is currently putting together the clinical trial plan for a Phase 2 clinical trial, which will be in patients with bacteremia, including those with endocarditis, which is caused by both MRSA and MSSA. It will be a multicenter, randomized, double blind, placebo controlled trial with a superiority comparison between CF-301 combined with the SOC antibiotics compared to placebo with the standard of care antibiotics. Endpoints will include elimination of bacteremia along with various clinical and microbiological outcomes. Safety, tolerability, and pharmacokinetics will also be examined. How many patients will be enrolled and how long the trial will take are still unknown at this point, however we anticipate that the trial will cost anywhere from $10 to $20 million to run. We anticipate the company finalizing the trial protocol and initiating the trial in the fourth quarter of 2016.

CF-404 Update

CF-404 is a mixture of monoclonal antibodies that target different strains of the influenza virus. The distinguishing characteristic of CF-404 is that the antibodies target conserved regions of the virus that are not prone to high rates of mutation. A new influenza vaccine is necessary each year due to the fact that the different strains of the influenza virus are constantly changing. By targeting the portions of the virus that are not prone to mutation, the company is able to develop one therapeutic that will not need to be continually reformulated.

ContraFect will be positioning CF-404 as a therapeutic option for the approximately 200,000 individuals who are hospitalized each year due to influenza, although the total number of influenza-related hospitalizations for the 2014-2015 influenza season was over 970,000. Preclinical data shows that CF-404 is effective in a mouse model of the H1N1 virus even when dosed up to 96 hours post-infection. This is in stark contrast to Tamiflu® (oseltamivir), an antiviral medication that must be administered within 24 hours of infection in the same model, as shown in the following figure.



Source: ContraFect Corp.

The company is planning on conducting additional manufacturing and pre-clinical studies to support filing an investigational new drug (IND) application in mid-2017, with initiation of Phase 1 clinical trials shortly thereafter.

Conclusion and Valuation

The positive results from the Phase 1 study were an important de-risking event for the company, as CF-301 does not appear to trigger any type of hypersensitivity reactions and was safe at the dose level that will be tested in the upcoming Phase 2 clinical trial. Our probability adjusted discounted cash flow model, which takes into account potential future revenues from CF-301 and CF-404, yields a valuation of $12 per share. We continue to be highly enthusiastic about the lysin technology and ContraFect's prospects, and believe that those interested in the anti-infective space should consider taking a close look at ContraFect.

PROJECTED INCOME STATEMENT

ContraFect Corp.
Income Statement

ContraFect Corp.	2015 A	Q1 A	Q2 E	Q3 E	Q4 E	2016 E	2017 E	2018 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	$15.0	$4.4	$3.5	$4.8	$5.3	$18.0	$18.0	$21.0
General & Administrative	$10.1	$4.7	$2.9	$3.0	$3.0	$13.6	$13.0	$14.0
Other Expenses	$0	$0	$0	$0	$0	$0	$0	$0
Operating Income	($25.1)	($9.2)	($6.4)	($7.8)	($8.3)	($31.7)	($31.0)	($35.0)
Operating Margin	-	-	-	-	-	-		
Non-Operating Expenses (Net)	($0.1)	$0.2	($0.1)	($0.1)	($0.1)	$0.1	($0.1)	($0.1)
Pre-Tax Income	($25.1)	($8.9)	($6.5)	($7.9)	($8.4)	($31.6)	($31.1)	($35.1)
Income Taxes Paid	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	**($25.1)**	**($8.9)**	**($6.5)**	**($7.9)**	**($8.4)**	**($31.6)**	**($31.1)**	**($35.1)**
Net Margin	-	-	-	-	-	-		
Reported EPS	**($1.08)**	**($0.32)**	**($0.23)**	**($0.28)**	**($0.27)**	**($1.11)**	**($0.89)**	**($0.92)**
YOY Growth	-	-	-	-	-	-		
Basic Shares Outstanding	23.3	27.5	27.5	28.0	31.0	28.5	35.0	38.0

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

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WEEKLY PRICE CHART



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