Zacks Small-Cap Research

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ContraFect Corp

(CFRX-NASDAQ)

CFRX: Final Logistics Being Completed For Initiation of Phase 2 Trial of CF-301 in mid-2017…

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 $10/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 (05/09/17)	$1.40
Valuation	**$10.00**

OUTLOOK

On May 8, 2017, ContraFect Corp. (CFRX) announced financial results for the first quarter of 2017 and provided a business update. The company exited the first quarter of 2017 with approximately $28.9 million in cash, cash equivalents, and marketable securities. We believe this will be sufficient to fund operations into the second quarter of 2018.

ContraFect is set to initiate a Phase 2 clinical trial of CF-301 in patients with bacteremia caused by *Staphylococcus aureus* in mid-2017. The company has the final investigational drug product and final logistics are being completed prior to initiation of patient enrollment.

SUMMARY DATA

52-Week High	**$3.56**
52-Week Low	**$1.40**
One-Year Return (%)	**-57.06**
Beta	**-0.79**
Average Daily Volume (sh)	**36,691**
Shares Outstanding (mil)	**42**
Market Capitalization ($mil)	**$58**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**45**
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 E	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	-$0.16 E	-$0.17 E	-$0.18 E	-$0.69 E
2018					-$0.63 E
2019					-$0.70 E

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WHAT'S NEW

Financial Update

On May 8, 2017, ContraFect Corp. (CFRX) announced financial results for the first quarter of 2017. As expected, the company did not report any revenues. The net loss for the quarter was $6.3 million, or $0.15 per share, and consisted of $4.2 million in R&D expenses and $2.1 million in G&A expenses. R&D expenses for the quarter were decrease by $0.2 million compared to the same time period in 2016 as a result of a decrease in spending on CF-404 cGMP manufacturing. G&A expenses were decreased by $2.6 million compared to the same time period in 2016 as a result of $2.0 million in severance costs recognized in 2016 along with a $0.6 million lower cost in non-cash share-based compensation.

Total cash burn for the quarter was $6.2 million, and the company had approximately $28.9 million in cash and cash equivalents as of Mar. 31, 2017. We believe this will be sufficient to fund operations into the second quarter of 2018, however the company will need to raise additional capital or attain some type of bridge funding to get to the end of the Phase 2 trial of CF-301, as results for that study are not anticipated until the end of 2018 or early 2019.

As of May 2, 2017, the company had approximately 41.7 million shares outstanding. In addition, there are approximately 5.1 million stock options and 20.3 million warrants for a fully diluted share count of approximately 67.1 million. The company recently increased the number of authorized shares from 100 million to 200 million.

Business Update

New Data Presented on CF-301

On April 19, 2017, ContraFect announced new data would be presented on CF-301 at the 27th European Congress of Clinical Microbiology and Infectious Disease (ECCMID). The company presented two posters, one on six-month follow up results from the initial Phase 1 clinical trial to better understand the safety profile of CF-301 and examine the resolution of anti-drug antibodies, and the other detailing the development of a new methodology for CF-301 susceptibility testing that was optimized for use in clinical testing laboratories.

Long-Term Immunology Follow-Up Results of Phase 1 Study: The Phase 1 escalating dose study of CF-301 involved a total of 20 subjects; 13 received CF-301 (4 each at 0.04 mg/kg, 0.12 mg/kg, and 0.25 mg/kg and 1 subject at 0.4 mg/kg) and 7 received placebo. Follow administration of CF-301, subjects had follow up visits on Days 5, 8, 14, 28, 90, and 180. The Day 90 and 180 visits included blood tests for analysis of CF-301 anti-drug antibodies (ADAs), CF-301 specific immunoglobulin E (IgE), and CF-301 specific basophil activation test (BAT). Eighteen subjects completed the Study Day 90 follow-up (2 withdrew from the study) and 15 completed the Day 180 visit (an additional 3 were lost to follow up).

Results showed that 9/13 subjects developed CF-301 specific ADAs following a single dose of CF-301, however the titers were waning or absent by day 180. There was no correlation between the magnitude of the ADA response and the dose of CF-301. One patient dosed with CF-301 had CF-301 specific IgE on Day 28 which was absent on Day 90 and 180. No CF-301 dosed patients were BAT-positive, however one placebo dosed patient was BAT-positive at Day 180. Overall, the data suggest that there is a low propensity to induce a hypersensitivity reaction upon a single dose of CF-301.

Development of an Antimicrobial Susceptibility Test (AST) for CF-301: A specific assay exists to test the susceptibility of *S. aureus* strains to CF-301 in the clinical setting. Unfortunately, this test does not provide reproducible minimal inhibitory concentration (MIC) determinations due to the unique characteristics of CF-301. By altering various parameters of the assay (e.g., growth media, excipients, growth temperature, etc.), ContraFect researchers were able to produce a robust and reproducible assay suitable for use in the upcoming Phase 2 clinical trial.

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 is planning to initiate a Phase 2 clinical trial for CF-301 in patients with bacteremia, including those with endocarditis, which is caused by both MRSA and methiciliin-sensitive strains of *Staphylococcus aureus*. The company met with both the FDA and the Medical and Healthcare products Regulatory Agency (MHRA) to discuss the design of the trial with positive feedback received from both agencies. The trial is scheduled to begin in mid-2017. It will be an international, multicenter, randomized, double blind, placebo controlled trial 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. 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.

The company has the CF-301 investigational drug product that has passed release specifications and the final logistics are being completed in order to begin dosing patients shortly. We anticipate that the Phase 2 trial will cost anywhere from $10 to $20 million to run and topline results should be available at the end of 2018 or beginning of 2019. The company is not planning to perform an interim analysis.

Conclusion and Valuation

The initiation of the upcoming Phase 2 clinical trial of CF-301 could be a positive catalyst for the shares, as ContraFect is expected to begin the trial in mid-2017. In addition, we are interested to hear about potential new preclinical lysin candidates from the collaboration with Rockefeller University. 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 $10 per share, and we believe that all investors interested in the anti-infective space should consider taking a close look at ContraFect.

PROJECTED INCOME STATEMENT

ContraFect Corp.
Income Statement

ContraFect Corp.	2016 A	Q1 A	Q2 E	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	$4.5	$5.0	$5.1	$18.8	$20.0	$25.0
General & Administrative	$11.4	$2.1	$2.4	$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)	($6.9)	($7.4)	($7.5)	($28.1)	($31.0)	($38.0)
Operating Margin	-	-	-	-	-			
Non-Operating Expenses (Net)	$5.0	($0.0)	($0.1)	($0.1)	($0.1)	($0.3)	($0.4)	($0.4)
Pre-Tax Income	($28.5)	($6.3)	($7.0)	($7.5)	($7.6)	($28.4)	($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)**	**($7.0)**	**($7.5)**	**($7.6)**	**($28.4)**	**($31.4)**	**($38.4)**
Net Margin	-	-	-	-	-			
Reported EPS	**($0.85)**	**($0.15)**	**($0.17)**	**($0.18)**	**($0.18)**	**($0.68)**	**($0.63)**	**($0.70)**
YOY Growth	-	-	-	-	-			
Basic Shares Outstanding	33.5	41.6	41.8	41.8	41.9	41.8	50.0	55.0

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

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