Zacks Small-Cap Research

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ContraFect Corp

(CFRX-NASDAQ)

CFRX: Phase 2 Trial of CF-301 to Initiate 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 (03/20/17)	$2.10
Valuation	**$10.00**

OUTLOOK

On March 14, ContraFect Corp. announced financial results for the fourth quarter and full year 2016. The company exited the year with $35.2 million in cash, cash equivalents, and marketable securities. This was due in part to raising $35 million in gross proceeds in July 2016. The company also received $2.1 million from a PRMRP grant from the U.S. Department of Defense to support the development of CF-301. We anticipate the current cash position to fund operations into the second quarter of 2018.

The company will be initiating a Phase 2 clinical trial for CF-301 in bacteremia patients in mid-2017. We anticipate topline results being reported at the end of 2018 or beginning of 2019. In addition, ContraFect has expanded the previous collaboration with Rockefeller University to identify additional lysin candidates targeting Gram-negative bacteria.

SUMMARY DATA

52-Week High	**$4.01**
52-Week Low	**$1.54**
One-Year Return (%)	**-41.18**
Beta	**-0.82**
Average Daily Volume (sh)	**65,774**
Shares Outstanding (mil)	**42**
Market Capitalization ($mil)	**$87**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**46**
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)
2016	0 A	0 A	0 A	0 A	0 A
2017	0 E	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	-$0.16 E	-$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 March 14, 2017, ContraFect Corp. (CFRX) announced financial results for the fourth quarter and full year ending Dec. 31, 2016. As expected, the company did not report any revenues for the quarter or the full year. Net income for the fourth quarter of 2016 was $0.6 million, or $0.01 per share, which was mostly due to a $7.3 million non-cash gain for the change in fair value of warrant liabilities. The company also reported $4.5 million in R&D expenses and $2.3 million in G&A expenses. For the full year, the company reported a net loss of $28.5 million, or $0.85 per share, which was comprised of $22.1 million in R&D expenses and $11.4 million in G&A expenses.

The company exited 2016 with approximately $35.2 million in cash, cash equivalents, and marketable securities. This was due in part to an underwritten public offering of 14 million shares of common stock at an offering price of $2.50 per share along with 14 million warrants with an exercise price of $3.00 per share. Total net proceeds to the company from the offering were $32.6 million. We believe the company has sufficient capital to fund operations into the second quarter of 2018.

As of Mar. 7, 2017, the company had approximately 41.7 million shares outstanding. In addition, there are approximately 4.7 million stock options and 20.3 million warrants for a fully diluted share count of approximately 66.6 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.

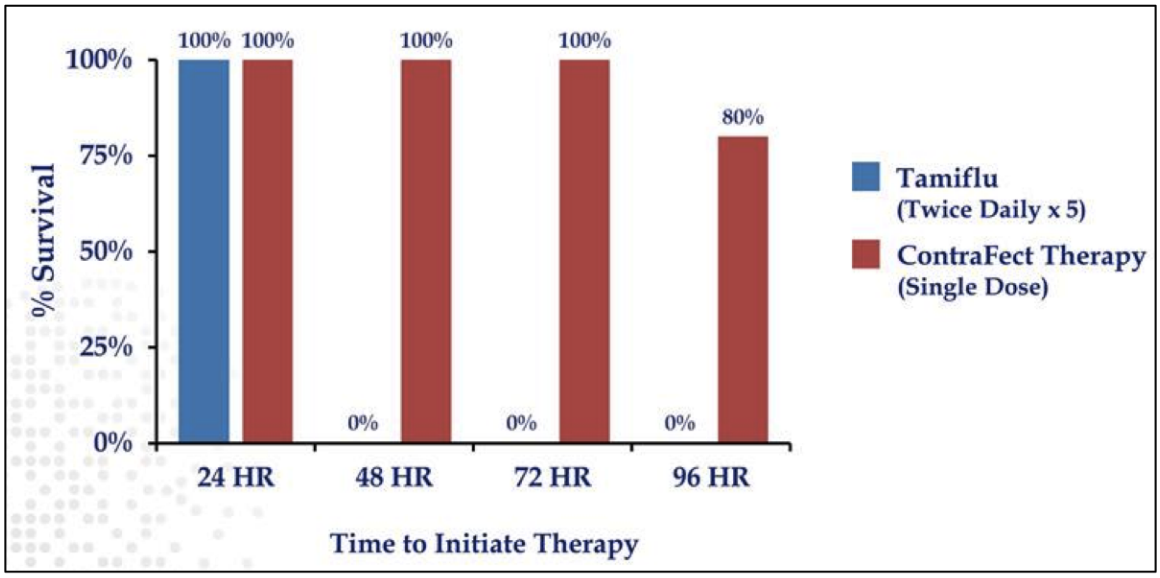
The company is planning to initiate a Phase 2 clinical trial for CF-301 in patients with bacteremia, including those with endocarditis, which is caused by both MRSA and methiciliin-sensitive strains of *Staphylococcus aureus*. The company met with both the FDA and the Medical and Healthcare products 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.

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.

CF-404

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.

ContraFect has completed the cGMP manufacturing of CF-404 to support Investigational New Drug (IND)-enabling activities. In January 2017, the company announced that the timelines for the IND filing are currently under review since the company is focusing the majority of its resources on the CF-301 program.

Expanded Research Collaboration with Rockefeller University

On November 14, 2016, ContraFect announced it entered into a three-year research collaboration with The Rockefeller University to identify new lysin therapeutic candidates targeting Gram-negative bacteria. The company currently has a research collaboration with Rockefeller and this agreement expands upon that collaboration and will focus on lysin therapeutic candidates that target Gram-negative pathogens. ContraFect's lead lysin CF-301 targets

S. aureus, which is a Gram-positive pathogen. Examples of Gram-negative pathogens include *Escherichia coli*, *Pseudomonas aeroginosa*, and *Klebsiella*. These bacteria can cause infections including pneumonia, bloodstream infections, wound infections, and meningitis, and many of them are becoming increasingly resistant to most available antibiotics.

CEO Takes Medical Leave

On March 13, 2017, ContraFect announced that CEO Steven Gilman will be on medical leave beginning on March 16, 2017. He will continue to serve as Chairman during his temporary leave of absence and he is expected to return to his role as CEO in the third quarter of 2017. For the duration of Dr.Gilman's absence, the Board has established an Interim Office of the Chief Executive Officer, which will consist of Cara Cassino, Executive Vice President of Research and Development and Chief Medical Officer, Natalie Bogdanos, General Counsel and Corporate Secretary, Michael Messinger, Senior Vice President, Finance, and Josh Muntner, Senior Vice President, Business Development. All of those individuals will assume the CEO duties on an interim basis and the Office of the CEO will report directly to a newly formed subcommittee of the Board.

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 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 E	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	$4.4	$4.5	$5.0	$5.1	$19.0	$20.0	$25.0
General & Administrative	$11.4	$2.3	$2.4	$2.4	$2.4	$9.5	$11.0	$13.0
Other Expenses	$0	$0	$0	$0	$0	$0	$0	$0
Operating Income	($33.5)	($6.7)	($6.9)	($7.4)	($7.5)	($28.5)	($31.0)	($38.0)
Operating Margin	-	-	-	-	-			
Non-Operating Expenses (Net)	$5.0	($0.1)	($0.1)	($0.1)	($0.1)	($0.4)	($0.4)	($0.4)
Pre-Tax Income	($28.5)	($6.8)	($7.0)	($7.5)	($7.6)	($28.9)	($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)**	**($6.8)**	**($7.0)**	**($7.5)**	**($7.6)**	**($28.9)**	**($31.4)**	**($38.4)**
Net Margin	-	-	-	-	-			
Reported EPS	**($0.85)**	**($0.16)**	**($0.17)**	**($0.18)**	**($0.18)**	**($0.69)**	**($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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