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ContraFect Corp. (CFRX-NASDAQ)

CFRX: Four Abstracts Published in 30th ECCMID Abstract Book; Financing Overhang Removed as Pfizer Makes Second Investment…

Based on our probability adjusted DCF model that takes into account potential future revenues from CF-301 in bacteremia along with the lysin pipeline, CFRX is valued at $22/share. This model is highly dependent upon continued clinical success of CF-301 and additional lysin products and will be adjusted accordingly based upon future clinical results.

Current Price (05/29/20)	$5.31
Valuation	**$22.00**

OUTLOOK

ContraFect Corp. (CFRX) recently announced that four abstracts were published in the 30th European Congress of Clinical Microbiology and Infectious Diseases (ECCMID) abstract book. Included was an abstract on the use of exebacase in four patients who had chronic, relapsing prosthetic joint infections. Two of the patients had septic arthritis and after one year follow up the outcome was favorable in those patients with the disappearance of clinical signs of septic arthritis. This is an early indication of an additional use for exebacase in the treatment of prosthetic *Staphylococcus aureus* infections.

The company recently completed a public financing that resulted in net proceeds of $48.8 million. In addition, a private placement was completed with Pfizer, the second such investment that Pfizer has made in ContraFect. We estimate the company now has sufficient capital to fund operations past the expected interim analysis of the Phase 3 DISRUPT trial, which will occur once the trial is 60% enrolled.

SUMMARY DATA

52-Week High	**$12.30**
52-Week Low	**$2.90**
One-Year Return (%)	**25.83**
Beta	**1.12**
Average Daily Volume (sh)	**284,093**
Shares Outstanding (mil)	**15**
Market Capitalization ($mil)	**$81**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**37**
Insider Ownership (%)	**4**
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 2019 Estimate	**-2.7**
P/E using 2020 Estimate	**-3.7**

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)
2019	0 A	0 A	0 A	0 A	0 A
2020	0 A	0 E	0 E	0 E	0 E
2021					0 E
2022					0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2019	$1.46 A	-$1.09 A	-$0.67 A	-$1.11 A	-$1.54 A
2020	-$0.49 A	-$0.33 E	-$0.27 E	-$0.28 E	-$1.29 E
2021					-$1.13 E
2022					-$1.03 E

WHAT'S NEW

Business Update

Four Abstracts Published in 30th ECCMID Abstract Book

On May 11, 2020, ContraFect Corp. (CFRX) announced four abstracts were published in the 30th European Congress of Clinical Microbiology and Infectious Diseases (ECCMID) abstract book. Both the on-site and online portion of ECCMID 2020 were cancelled due to the ongoing coronavirus epidemic and accepted abstracts were recently published. Contrafect's published abstracts included two on exebacase, one on CF-370 (a lysin targeting Pseudomonas aeruginosa), and one on amurin peptides.

Therapeutic innovation in bone and joint infections: evaluation of the activity of exebacase (CF-301 lysin) on clinical strains belonging to *Staphylococcus epidermidis* species.

Four patients with post-operative prosthetic joint infections (PJIs) have been treated with exebacase under Temporary Authorizations for Use from the French National Agency for Medicines and Health Products Safety in collaboration with Dr. Tristan Ferry at the Hôpital de la Croix Rousse in Lyon, France.

The abstract describes the four patients as two having signs of septic arthritis and two of them having fistula. Importantly, no adverse events occurred during arthroscopy. Following one year of follow up, the outcome was favorable in the two septic arthritis patients with disappearance of clinical signs of septic arthritis.

The patients that have been treated thus far had longstanding, treatment refractory PJIs. Following intra-articular treatment, the promising signals seen in these patients has led to the temporary authorization to use exebacase being extended to patients with *Staphylococcal* PJI that occurs shortly after surgery to hopefully avoid significant damage to the joint.

Biofilm formation in prosthetic joints is a very challenging infection to clear with traditional antibiotics, which typically leads to additional surgery and possibly replacement of the joint to ultimately get rid of the infection. The company has previously shown exebacase is able to rapidly clear biofilms, as shown in the following figures, thus we view the application of the drug in treating difficult-to-clear prosthetic infections as a natural next step in its development life cycle.

Source: ContraFect Corp.

Exebacase resensitizes methicillin-resistant *Staphylococcus aureus* (MRSA) to oxacillin in a rabbit model of infective endocarditis

Exebacase was tested in a rabbit model of endovascular MRSA infection with multiple dose regimens of exebacase administered alongside oxacillin. Results showed that combination therapy reduced MRSA counts by 5 $\log_{10}$ CFU/g tissue compared to oxacillin treatment alone, exebacase alone, and growth controls (P<0.0001). The reduction in MRSA CFUs is indicative of resensitization of MRSA to oxacillin, and may support the use of exebacase to increase susceptibility of resistant strains of *S. aureus* to different classes of antibiotics.

First evidence of systemic efficacy of a pathogen-targeted, engineered lysin (GN-370) against carbapenem-resistant *Pseudomonas aeruginosa (P. aeruginosa),* in a rabbit pneumonia model

CF-370 is an engineered lysin targeting *Pseudomonas aeruginosa*, a Gram-negative bacterial species that is listed as a serious threat in the Centers for Disease Control and Prevention (CDC) 2019 Antibiotic Resistance Threats

Report. This abstract reported the results of CF-370 in a rabbit pneumonia model. Treatment with exebacase resulted in 100% survival compared to only 40% survival in vehicle control animals. In addition to showing a survival benefit, CF-370 showed synergistic effects with meropenem as bacterial counts in all target tissues decreased by an additional 2 log_{10} CFU/g versus meropenem or CF-370 alone ($P \leq 0.02$). This *in vivo* proof-of-concept establishes that it is possible to successfully target a Gram negative bacteria with a lysin.

First report of the discovery of amurin peptides: direct lytic agents with broad activity against carbapenem-resistant *Enterobacteriaciae, Acinetobacter*, and *Pseudomonas*, including colistin-resistant strains

The following table shows three lead amurin peptide (AM) candidates that exhibit potent in vitro activity as judged by low minimal inhibitory concentrations (MICs) against clinical infection isolates including Enterobacteriaceae, A. baumannii, and P. aeruginosa. Those strains include those that are carbapenem-resistant and resistant to multiple antibiotics, including antibiotics of last resort.

Panel (no. of strains)	AM1	AM2	AM3
	(MIC_{90})		
Enterobacteriaceae (46)	1	1	0.5
Acinetobacter baumannii (41)	1	1	0.5
Pseudomonas aeruginosa (55)	1	1	0.5
Imipenem/relebactam (24)	1	1	0.5
Isolates with new or novel resistance (11)	1	0.25	0.125

Source: ContraFect Corp.

Update on Phase 3 DISRUPT Trial

In January, 2020, ContraFect announced the first patient had been dosed in the Phase 3 DISRUPT (Direct Lysis of *Staph aureus* Resistant Pathogen Trial) study of exebacase in patients with *Staphylococcus aureus* bacteremia, including right-sided endocarditis (NCT04160468). The randomized, double blind, placebo controlled trial is being conducted at centers in the U.S. and will enroll approximately 350 patients randomized 2:1 to receive either exebacase or placebo, with all patients receiving standard of care antibiotics. Thus far, the trial is continuing to enroll patients during the ongoing coronavirus pandemic and clinical trial sites remain open.

The primary endpoint of the trial will be clinical response at Day 14 in patients with methicillin-resistant *S. aureus* (MRSA) bacteremia, including right-sided endocarditis. Clinical response is defined using objective clinical criteria including: 1) resolution of *S. aureus* bacteremia/right-sided endocarditis signs and symptoms that were present at baseline; 2) no new signs or symptoms of bacteremia/right-sided endocarditis; 3) no complications of bacteremia/right-sided endocarditis; 4) no changes in anti-staphylococcal antibiotics after treatment with study drug due to persistence, worsening, or recurrence of signs or symptoms of bacteremia/right-sided endocarditis; 5) blood cultures negative for S. aureus by Day 14; and 6) the patient is alive. Clinical response is being determined by an independent, blinded clinical adjudication committee.

Key secondary endpoints include clinical response rate at Day 14 for all *S. aureus* bacteremia patients (including both MRSA and methicillin-sensitive *S. aureus* [MSSA]), 30-day all-cause mortality in MRSA patients, and clinical response at Day 60. The company will also evaluate the impact of treatment with exebacase on length of hospital stay, length of stay in the intensive care unit, and 30-day readmission rates for both all-cause and *S. aureus* infection readmissions. An interim futility analysis will be conducted after the first 60% of patients enrolled into the trial are evaluable for efficacy.

The following table shows the statistical parameters for the primary efficacy endpoint and key secondary efficacy endpoints from the trial. The primary endpoint is 86% powered to show a 28% increase in clinical response rate at Day 14 with the use of exebacase plus standard of care antibiotics compared to standard of care antibiotics alone.

	Primary Efficacy Endpoint: Clinical Response at Day 14 (MRSA Patients)	Secondary Efficacy Endpoint: Clinical Response at Day 14 (All *Staph aureus* Patients)	Secondary Efficacy Endpoint: Mortality (MRSA Patients)
Target difference	28% increase over SOC antibiotics alone	16% increase over SOC antibiotics alone	17% decrease from SOC antibiotics alone
Power	86%	83%	80%
Sample size	135 patients	339 patients	135 patients

Source: ContraFect Corp.

Breakthrough Therapy Designation for Exebacase

On Feb. 24, 2020, ContraFect announced that the US FDA has granted Breakthrough Therapy designation to exebacase for the treatment of MRSA bacteremia, including right-sided endocarditis, when used in conjunction with standard of care antibiotics. The FDA established the Breakthrough Therapy program to speed the development of medicines for serious or life-threatening diseases with preliminary clinical evidence that may show the investigational product could substantially improve at least one clinically significant endpoint over currently available therapies.

Breakthrough Therapy designation was granted to exebacase based on data from the Phase 2 clinical trial showing treatment with exebacase led to a 42.8 percent higher responder rate at Day 14 in patients with MRSA infections compared to treatment with standard of care antibiotics alone (74.1% vs. 31.3%; *P*=0.01). Exebacase carries both Breakthrough Therapy and Fast Track designation, which will allow for a rolling BLA submission and priority review.

Financial Update

On May 15, 2020, ContraFect announced financial results for the first quarter of 2020. As expected, the company did not report any revenue for the first quarter of 2020. Net loss for the three months ending Mar. 31, 2020 was $7.6 million, or $0.49 per share, compared to net income of $11.6 million, or $1.46 per share, for the comparable period in 2019. The decrease was the result of the decrease in the non-cash gain for the change in fair value of warrant liabilities. R&D expenses for the first quarter of 2020 were $5.1 million, compared to $4.1 million in the first quarter of 2019. The increase was primarily due to increased manufacturing costs and development costs for CF-296. G&A expenses in the first quarter of 2020 were $3.0 million, compared to $2.3 million for the first quarter of 2019. The increase was primarily due to an increase in administrative headcount and personnel costs along with legal fees.

As of Mar. 31, 2020, ContraFect had approximately $16.7 million in cash, cash equivalents, and marketable securities. In May 2020, the company raised net proceeds of approximately $48.8 million in a public offering and separately raised $3 million from a private placement with Pfizer, Inc. This was the second investment in ContraFect by Pfizer, with the first coming in Dec. 2019. We estimate that ContraFect now has sufficient capital to fund operations past the expected interim analysis for the Phase 3 DISRUPT trial, which will occur once the trial is 60% enrolled. Following the recent financing's we estimate that the company has approximately 27.8 million common shares outstanding and when factoring in warrants and stock options a fully diluted share count of approximately 42.0 million.

Conclusion

We are glad to hear that the ongoing coronavirus epidemic is not having a substantial effect on the DISRUPT trial and that the clinical trial sites remain open and continue to enroll patients. We look forward to additional guidance from the company on when 60% enrollment, and the interim futility analysis, will occur. The recent presentations on Gram-negative lysins and amurins show that ContraFect is building a deep pipeline of advanced anti-infective agents beyond exebacase. Given the robust gains in the biotech sector over the past few months we view it as a good time for companies to raise cash, and the fact that Pfizer has made a second investment is a very promising sign. After accounting for the recent financings our valuation has decreased to $22, however we continue to view ContraFect as a top pick among small cap biotech stocks.

PROJECTED FINANCIALS

ContraFect Corp.	2019 A	Q1 A	Q2 E	Q3 E	Q4 E	2020 E	2021 E	2022 E
CF-301 (Bacteremia)	$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	$18.1	$5.1	$4.7	$4.8	$5.0	$19.6	$21.0	$23.0
General & Administrative	$9.8	$3.0	$2.5	$2.6	$2.7	$10.8	$10.5	$11.0
Other Expenses	$0	$0	$0	$0	$0	$0	$0	$0
Operating Income	($27.9)	($8.1)	($7.2)	($7.4)	($7.7)	($30.4)	($31.5)	($34.0)
Operating Margin		-	-	-	-			
Non-Operating Expenses (Net)	$15.1	$0.5	$0.0	$0.0	$0.0	$0.5	$0.0	$0.0
Pre-Tax Income	($12.8)	($7.6)	($7.2)	($7.4)	($7.7)	($29.9)	($31.5)	($34.0)
Income Taxes Paid	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	**($12.8)**	**($7.6)**	**($7.2)**	**($7.4)**	**($7.7)**	**($29.9)**	**($31.5)**	**($34.0)**
Net Margin		-	-	-	-			
Reported EPS	**($1.54)**	**($0.49)**	**($0.33)**	**($0.27)**	**($0.28)**	**($1.29)**	**($1.13)**	**($1.03)**
YOY Growth		-	-	-	-			
Basic Shares Outstanding	8.3	15.3	22.0	27.8	27.8	23.2	27.8	33.0

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

HISTORICAL STOCK PRICE

Source: Zacks Investment Research

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