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ContraFect Corp. (CFRX-NASDAQ)

CFRX: Enrollment Continues in Phase 3 Trial of Exebacase…

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 (11/24/20)	$5.12
Valuation	**$22.00**

OUTLOOK

ContraFect Corp. (CFRX) is currently conducting the Phase 3 DISRUPT Trial, which is evaluating exebacase for the treatment of patients with bacteremia caused by *Staphylococcus aureus*. The trial is expected to enroll approximately 350 patients randomized 2:1 to receive exebacase or placebo in addition to standard of care antibiotics for bacteremia caused by *S. aureus* and methicillin-resistant *S. aureus* (MRSA) bacteremia, including right-sided endocarditis. An interim futility analysis will be performed once the first 60% of patients enrolled into the trial are evaluable for efficacy.

The company recently received an award of up to $18.9 million from CARB-X to advance its second product candidate, CF-370, which is an engineered lysin targeting Pseudomonas aeruginosa. The funding will cover IND-enabling activities to advance CF-370 toward future Phase 1 clinical trials.

SUMMARY DATA

52-Week High	**$12.30**
52-Week Low	**$2.93**
One-Year Return (%)	**34.77**
Beta	**1.06**
Average Daily Volume (sh)	**106,174**
Shares Outstanding (mil)	**28**
Market Capitalization ($mil)	**$142**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**57**
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	**-3.6**
P/E using 2020 Estimate	**-3.1**

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 A	0 A	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	-$0.88 A	$0.12 A	-$0.28 E	-$1.30 E
2021					-$1.13 E
2022					-$1.03 E

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WHAT'S NEW

Business Update

Exebacase Expanded Access Program Initiated

On October 26, 2020, ContraFect Corp. (CFRX) announced the initiation of an expanded access program for exebacase to make it available to COVID-19 patients that are suffering from persistent bacteremia caused by *Staphylococcus aureus*. Exebacase will be available to use at clinical sites that are participating in the ongoing Phase 3 DISRUPT trial for COVID-19 patients who are severely ill with *S. aureus* bacteremia despite treatment with standard of care antibiotics. It is common for patients suffering from respiratory viral infections to develop secondary infections with opportunistic pathogens. There are reports of secondary bacterial infections in COVID-19 patients (Stat News), and *S. aureus* is a common cause of these secondary infections. This is the second expanded access program for exebacase, with the other being for the treatment of post-operative prosthetic join infections (PJIs) under Temporary Authorizations for Use from the French National Agency for Medicines and Health Products Safety.

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 *S. 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.

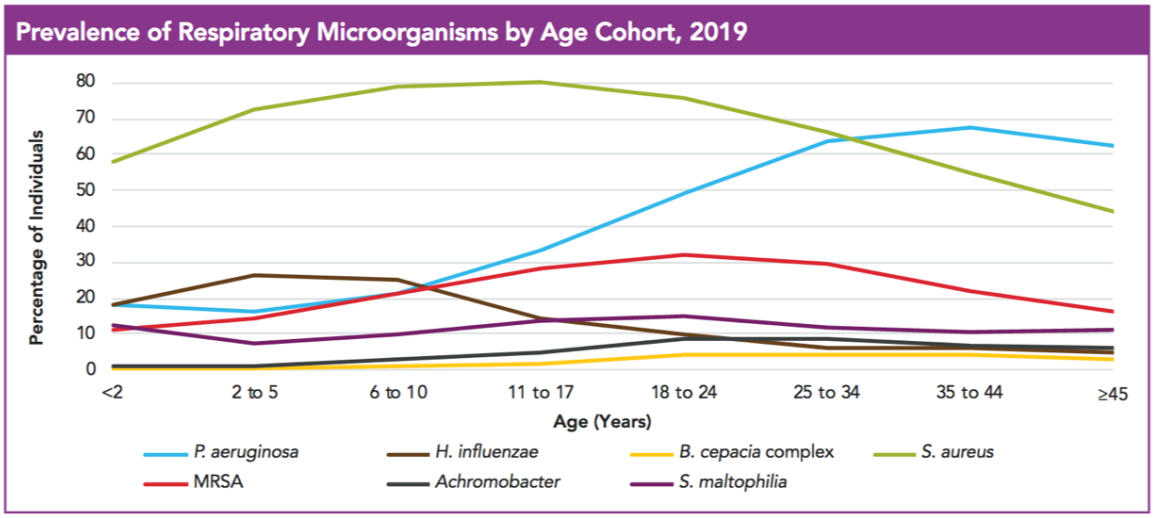
	Primary Efficacy Endpoint: Clinical Response at Day 14 (MRSA Patients)	Secondary Efficacy Endpoint: Clinical Response at Day 14 (All *Staph aureus* Patients)	Secondary Efficacy Endpoint: Mortality (MRSA Patients)
Target difference	28% increase over SOC antibiotics alone	16% increase over SOC antibiotics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

Source: ContraFect Corp.

Additional Funding for P. aeruginosa Program

In August 2020, ContraFect announced an initial funding agreement with the Cystic Fibrosis Foundation to study the effect of using direct lytic agents against Gram-negative pathogens that commonly afflict cystic fibrosis (CF) patients. The hallmark of CF is a thick, sticky mucus build up in various organs throughout the body, particularly in

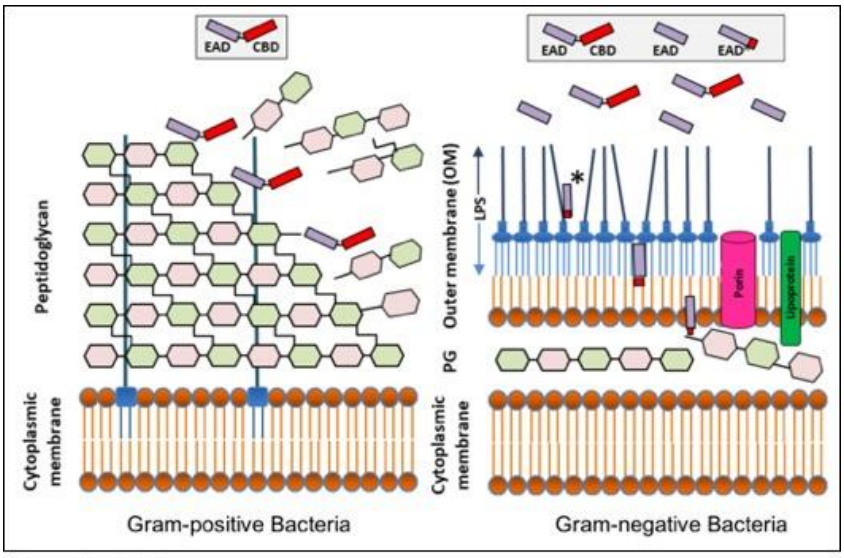
the lungs. The most serious complication associated with CF is difficulty in breathing due to recurrent lung infections. Lung disease in patients with CF results from airway blockage and resulting inflammation. The build up of mucus is an ideal environment for bacteria to grow, and the inflammation and repeated infections result in injury and structural changes to the lungs. The following chart, derived from the 2019 Cystic Fibrosis Foundation Patient Registry, shows that *Pseudomonas aeruginosa* makes up a considerable proportion of lung infections in CF patients, particularly as they get older. These infections are very difficult to treat, thus necessitating the need for improved therapeutics.



Source: CF Patient Registry, 2019

Funding from the CF Foundation is in addition to an award of up to $18.9 million from CARB-X (Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator), a global non-profit partnership dedicated to supporting the development of new antibacterial treatments, to support the IND-enabling activities for CF-370, an engineered lysin targeting *P. aeruginosa*. The award is for an initial funding of $4.9 million, with additional funds dispersed based upon project milestones.

In December 2019, ContraFect first announced CF-370 as the lead engineered lysin development candidate targeting a Gram-negative bacterial species. The following figure shows how lysins are effective against Gram-positive bacteria due to their ability to easily interact with the peptidoglycan layer. However, Gram-negative bacteria have an outer membrane that acts as a barrier against most lysins, thus preventing them from reaching the peptidoglycan layer. While the majority of purified Gram-negative lysins have no antimicrobial activity, there are a select few that have some activity in low ionic strength buffers (indicated by the asterisk in the following figure on the right). It is these lysins that ContraFect used as lead compounds to modify in order to increase their anti-microbial activity, with CF-370 emerging as the lead candidate from this research.



Source: ContraFect Corp.

ContraFect previously presented the first evidence of systemic efficacy of CF-370 against a carbapenem-resistant *P. aeruginosa* rabbit pneumonia model. Treatment with CF-370 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 study established that it is possible to successfully target Gram-negative bacteria with a lysin.

Financial Update

On November 13, 2020, ContraFect announced financial results for the third quarter of 2020. As expected, the company did not report any revenue for the third quarter of 2020. The company reported net income for the three months ending September 30, 2020 of $3.4 million, or $0.12 per share, compared to a net loss of $5.4 million, or $0.67 per share, for the three months ending September 30, 2019. After adjusting for the dilutive impact of the change in fair value of warrant liabilities, the company reported a net loss of $5.4 million, or $0.19 per diluted share, for the third quarter of 2020. R&D expenses for the third quarter of 2020 were $4.7 million, compared to $5.3 million for the third quarter of 2019. The decrease was primarily due to decreased internal and external research costs. G&A expenses were $2.6 million for third quarter of 2020, compared to $2.4 million for the third quarter of 2019. The increase was primarily due to increased professional fees and insurance costs.

As of September 30, 2020, ContraFect had approximately $50.2 million in cash, cash equivalents, and marketable securities. We estimate that ContraFect 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. As of November 6, 2020, ContraFect had approximately 27.8 million shares outstanding and, when including stock options and warrants, a fully diluted share count of 42.0 million.

Conclusion

Despite the ongoing coronavirus pandemic, clinical trial sites remain open for the DISRUPT trial and ContraFect has continued enrolling patients. We look forward to additional guidance from the company on when 60% enrollment, and the interim futility analysis, will occur. The support from the CF Foundation and CARB-X for CF-370 is a nice validation of the company's technology and will aid in getting the IND-enabling studies completed and the compound in the clinic. With no changes to the model our valuation remains at $22.

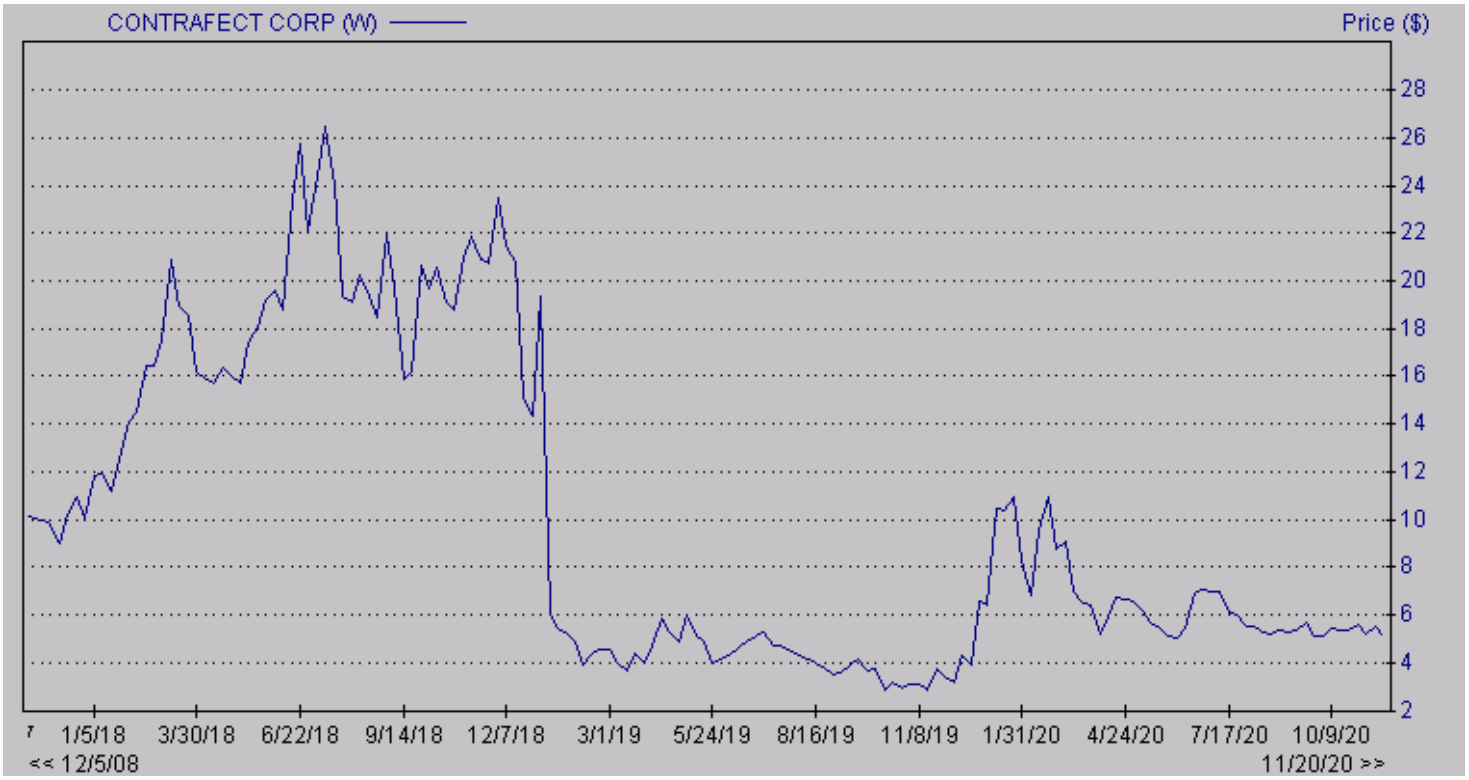
PROJECTED FINANCIALS

ContraFect Corp.	2019 A	Q1 A	Q2 A	Q3 A	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	$5.5	$4.7	$5.0	$20.4	$21.0	$23.0
General & Administrative	$9.8	$3.0	$2.6	$2.6	$2.7	$10.9	$10.5	$11.0
Other Expenses	$0	$0	$0	$0	$0	$0	$0	$0
Operating Income	($27.9)	($8.1)	($8.2)	($7.3)	($7.7)	($31.2)	($31.5)	($34.0)
Operating Margin		-	-	-	-			
Non-Operating Expenses (Net)	$15.1	$0.5	($9.5)	$10.8	$0.0	$1.8	$0.0	$0.0
Pre-Tax Income	($12.8)	($7.6)	($17.6)	$3.4	($7.7)	($29.5)	($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)**	**($17.6)**	**$3.4**	**($7.7)**	**($29.5)**	**($31.5)**	**($34.0)**
Net Margin		-	-	-	-			
Reported EPS	**($1.54)**	**($0.49)**	**($0.88)**	**$0.12**	**($0.28)**	**($1.30)**	**($1.13)**	**($1.03)**
YOY Growth		-	-	-	-			
Basic Shares Outstanding	8.3	15.3	20.0	27.8	27.8	22.7	27.8	33.0

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

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