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David Bautz, PhD
312-265-9471
dbautz@zacks.com

scr.zacks.com
10 S. Riverside Plaza, Chicago, IL 60606

ContraFect Corp. (CFRX-NASDAQ)

CFRX: Ready to Meet with the FDA Regarding Phase 3 Plan for 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 $4/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 (08/16/19)	$0.39
Valuation	**$4.00**

OUTLOOK

On August 9, 2019, ContraFect Corp. announced financial results for the second quarter of 2019 and provided a business update. The company has submitted all required documents ahead of the upcoming meeting with the FDA regarding the company's proposed plan for a Phase 3 trial for exebacase. We anticipate learning the outcome of this meeting in the coming months.

ContraFect has recently presented a plethora of new data on exebacase and other developmental lysins at scientific conferences and through peer-reviewed publications. In addition, the company was recently awarded a $7.2 million grant to develop CF-296, an engineered variant of exebacase that shows promise as a therapy for bone and joint infections in preclinical models.

SUMMARY DATA

52-Week High	**$2.47**
52-Week Low	**$0.36**
One-Year Return (%)	**-80.30**
Beta	**0.07**
Average Daily Volume (sh)	**107,020**
Shares Outstanding (mil)	**79**
Market Capitalization ($mil)	**$31**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**39**
Insider Ownership (%)	**7**
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 2018 Estimate	**-3.7**
P/E using 2019 Estimate	**-1.0**

Risk Level	**High**
Type of Stock	**Small-Blend**
Industry	**Med-Drugs**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2018	0 A	0 A	0 A	0 A	0 A
2019	0 A	0 A	0 E	0 E	0 E
2020					0 E
2021					0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2018	-$0.26 A	-$0.27 A	-$0.06 A	$0.07 A	-$0.50 A
2019	$0.15 A	-$0.11 A	-$0.08 E	-$0.08 E	-$0.14 E
2020					-$0.36 E
2021					-$0.39 E

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Business Update

Meeting with the FDA Regarding Exebacase Phase 3 Plan

ContraFect Corp. (CFRX) is developing exebacase (CF-301) as the company's lead lysin product. Lysins are naturally occurring anti-bacterial hydrolytic enzymes that are produced by bacteriophages, which are virus' that infect and kill bacteria. The company previously reported positive results from a Phase 2 clinical trial of exebacase in patients with bacteremia caused by *Staphylococcus aureus*, including those with endocarditis. Results showed a 43% improvement in responder rate at Day 14 for patients with methicillin-resistant *S. aureus* (MRSA) treated with exebacase + standard of care (SOC) antibiotics compared to SOC along (*P*=0.010).

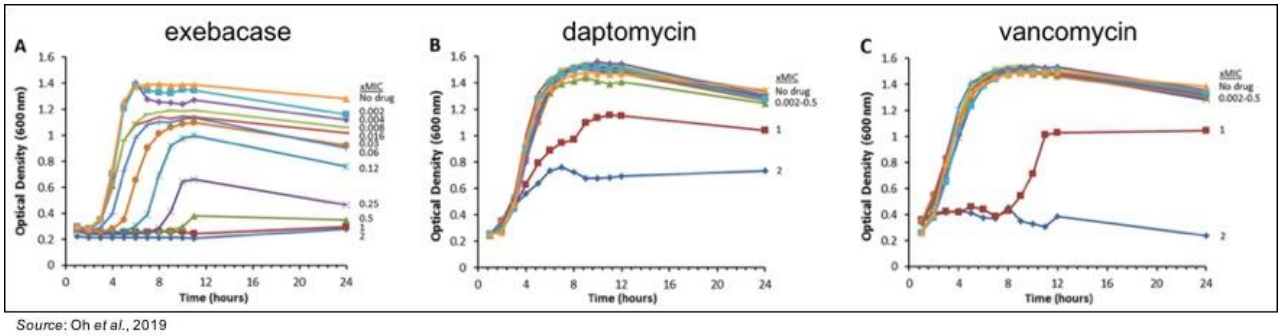
The company has submitted all required documentation to the FDA ahead of the upcoming 'End-of-Phase 2' meeting, at which time the company hopes to gain agreement with the agency on the design for a Phase 3 clinical trial. We anticipate the meeting taking place this quarter and the company providing an update following the receipt of meeting minutes. This should allow for the Phase 3 trial to initiate toward the end of 2019 or in the first half of 2020.

Postexposure and sub-MIC Growth Inhibition by Exebacase

In May 2019, ContraFect announced the publication of an article titled "Postantibiotic and Sub-MIC Effects of Exebacase (Lysin CF-301) Enhance Antimicrobial Activity against *Staphylococcus aureus*" was published in the peer-reviewed journal *Antimicrobial Agents and Chemotherapy* (Oh *et al*., 2019). The paper describes the results of *in vitro* experiments examining the postantibiotic effect (PAE), postantibiotic sub-MIC effect (PA-SME), and the sub-MIC effect (SME) of exebacase. The PAE is a suppressed phase of bacterial growth that persists until normal bacterial growth resumes following exposure to an antimicrobial agent. The PA-SME is suppressed growth during sub-MIC exposures to an antimicrobial agent. The SME measures the effect of sub-inhibitory drug concentrations on bacterial growth that were not previously exposed to antibiotics.

Fourteen strains of *S. aureus* were tested with exebacase or daptomycin to determine the PAE, PA-SME, and SME. The mean PAE for exebacase was 4.8 hours compared to a mean PAE of 2.5 hours for daptomycin. Mean PA-SME and SME values were 5.4 to 9.3 hours and 1.3 to 9.8 hours, respectively, for exebacase and 2.3 to 3.1 hours and 0.31 to 1.7 hours, respectively, for daptomycin. These results clearly show a superior postexposure effect for exebacase compared to daptomycin.

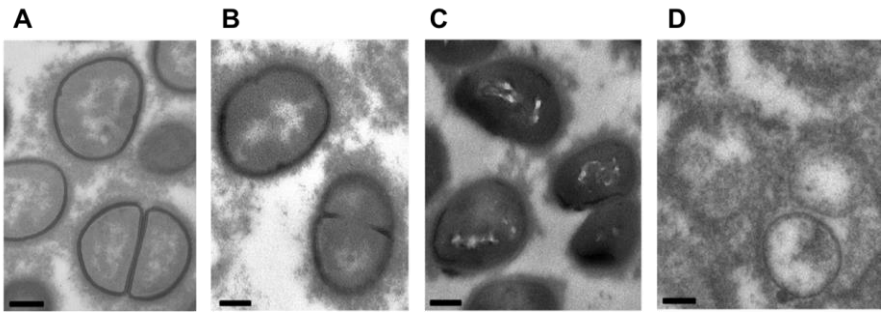
The following figures show how sub-MIC concentrations of exebacase alter growth kinetics of *S. aureus* while no such effect is seen with daptomycin or vancomycin. Figure A shows that exposures to exebacase ranging from 0.008x to 0.5x MIC diminished exponential growth and increased the lag phase while the same effect is not seen with daptomycin (Figure B) or vancomycin (Figure C) at sub-MIC concentrations. These experiments were performed in 100% human serum to better recapitulate the intended clinical use of exebacase as an intravenously administered therapeutic.



Source: Oh *et al.*, 2019

Sub-MIC concentrations of exebacase disrupt growth through alterations to the cell wall membrane. The following figures show the effects of Sub-MIC concentrations of exebacase on *S. aureus* morphology following one-hour exposure in human serum. Figure A shows a healthy cell with a clearly defined cell wall. This is in contrast to the

poorly defined and highly diffuse cell walls upon exposure to 0.1x MIC (Figure B) and 0.05x MIC (Figure C). The impact on cell wall structure is distinct from the overt lysis seen upon exposure to concentrations at or above the MIC (Figure D).



Source: Oh *et al.*, 2019

The overall conclusion from these studies is that the antibacterial effects demonstrated by exebacase are due to more than just direct lytic action. The post-exposure and sub-MIC effects can contribute to reduced bacterial growth and may help to augment the effect of standard of care antibiotics, all while not contributing to the selection of resistant clones.

Multiple Presentations at ASM Microbe 2019

In June 2019, ContraFect announced multiple poster presentations at the American Society for Microbiology (ASM) Microbe 2019 meeting, including the selection of one of the posters for an Outstanding Abstract Award, which was awarded to an abstract that detailed the pharmacokinetic properties of exebacase with repsect to efficacy in animal models. An overview of the posters is provided below.

PK-PD Relationship and PK Driver of Efficacy of the Novel Antibacterial Lysin Exebacase (CF-301) in Pre-Clinical Models – *ASM Outstanding Abstract Award*
This poster described the relationship between exebacase exposure and efficacy in four animal species (mice, rats, rabbits, and dogs) through various routes of administration (IV bolus, IV infusion, SC) at various dosing regimens (0.03 – 50 mg/kg) at frequencies of once a day to once every eight hours. The conclusion of the study was that AUC is a species dependent variable that is not a good means of predicting efficacy, however AUC/MIC ratio was appropriate for predicting efficacy regardless of species, so long as both AUC and MIC are determined for the corresponding species.

Lysins Exhibit Potent Bactericidal Activity, Synergy and Antibiofilm Effects against *Pseudomonas aeruginosa* in Human Serum and Pulmonary Surfactant

This study examined the bacteriolytic activities of four lead lysins against *Pseudomonas aeruginosa*. The results showed that each lysin had MIC values ≤ 2 μg/mL, showed synergism with a range of antibiotics, and exhibited potent anti-biofilm activity. In addition, rapid bactericidal activity was observed within five minutes of treatment.

Pharmacodynamic Assessment of Lysin CF-301 (exebacase) in Addition to Daptomycin against *Staphylococcus aureus* in the Neutropenic Murine Thigh Infection Model

Bacteriophage Lysin CF-301 (Exebacase) in Addition to Daptomycin in a Simulated Endocardial Vegetation (SEV) PK/PD Model

CF-301 and Daptomycin Treatment of Methicillin-Resistant *Staphylococcus aureus* Associated Experimental Osteomyelitis
These studies all tested the effect of exebacase and daptomycin both together and separately in various animal models. In each of those studies, the co-administration of exebacase and daptomycin was superior to the use of either agent on its own.

$7.2 Million Grant to Fund Next-Generation Exebacase

In June 2019, ContraFect announced that the Military Infectious Diseases Research Program (MIDRP), United States Army Medical Research and Development Command (USAMRDC) has awarded the company $7.2 million in

funding over three years to advance CF-296, an engineered variant of exebacase that could potentially improve clinical outcomes for patients with *S. aureus* bone and joint infections, through IND-enabling studies.

Financial Update

On August 9, 2019, ContraFect announced financial results for the second quarter of 2019. As expected, the company did not report any revenues for the quarter. R&D expenses for the second quarter of 2019 were $4.8 million compared to $5.3 million for the second quarter of 2018. The decrease was primarily due to decreased spending related to the Phase 2 clinical trial of exebacase partially offset by an increase in external research and licensing costs. G&A expenses were $2.6 million for the second quarter of 2019 compared to $2.2 million for the second quarter of 2018. The increase was primarily due to an increase in intellectual property and legal fees partially offset by a decrease in personnel costs. Net loss for the second quarter of 2019 was $8.7 million, or $0.11 per share, compared to a net loss of $20.1 million, or $0.27 per share, in the second quarter of 2018. The decrease in net loss was due to a decrease in the non-cash expense associated with the change in fair value of warrant liabilities.

As of June 30, 2019, ContraFect had cash, cash equivalents, and marketable securities of approximately $14.2 million. We estimate the company has sufficient capital to fund operations through the end of 2019. As of Aug. 7, 2019, the company had approximately 79.4 million shares outstanding and when factoring in warrants and stock options a fully diluted share count of approximately 122.1 million shares.

Conclusion

We are looking forward to learning additional details about ContraFect's plan for a Phase 3 study for exebacase following the company's meeting with the FDA. We continue to believe that a Phase 3 trial will commence either toward the end of 2019 or in the first half of 2020. The data presented at ASM Microbe 2019 further supports the efficacy of exebacase, particularly when used in conjunction with standard of care antibiotics, and the data showing efficacy of lead lysin candidates for the treatment of *P. aeruginosa* infections is very encouraging. Our valuation remains at $4.

PROJECTED FINANCIALS

ContraFect Corp.	2018 A	Q1 A	Q2 A	Q3 E	Q4 E	2019 E	2020 E	2021 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	$22.4	$4.1	$4.8	$5.2	$5.3	$19.4	$24.0	$28.0
General & Administrative	$8.7	$2.3	$2.6	$2.3	$2.3	$9.5	$9.5	$10.0
Other Expenses	$0	$0	$0	$0	$0	$0	$0	$0
Operating Income	($31.1)	($6.4)	($7.4)	($7.5)	($7.6)	($28.9)	($33.5)	($38.0)
Operating Margin		-	-	-	-			
Non-Operating Expenses (Net)	($6.6)	$17.9	($1.3)	$0.0	$0.0	$16.7	$0.0	$0.0
Pre-Tax Income	($37.7)	$11.6	($8.7)	($7.5)	($7.6)	($12.2)	($33.5)	($38.0)
Income Taxes Paid	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	**($37.7)**	**$11.6**	**($8.7)**	**($7.5)**	**($7.6)**	**($12.2)**	**($33.5)**	**($38.0)**
Net Margin		-	-	-	-			
Reported EPS	**($0.50)**	**$0.15**	**($0.11)**	**($0.08)**	**($0.08)**	**($0.14)**	**($0.36)**	**($0.39)**
YOY Growth		-	-	-	-			
Basic Shares Outstanding	76.1	79.4	79.4	90.0	91.0	85.0	92.0	98.0

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

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