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ContraFect Corp. (CFRX-NASDAQ)

CFRX: R&D Symposium Highlights Positive Data 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 (05/20/19)	$0.49
Valuation	**$4.00**

OUTLOOK

On May 14, 2019, ContraFect Corp. (CFRX) held an R&D symposium to discuss the potential for direct lytic agents, including lysins and amurins, as anti-infectives. Included in the discussion was an overview of the company's lead development product, exebacase, along with results from the Phase 2 clinical trial of exebacase in patients with bacteremia caused by *Staphylococcus aureus*. New data presented by the company included health economic data showing that treatment with exebacase decreased the median number of hospital days from 10.0 in the standard of care (SOC) only group to 6.0 in the exebacase + SOC group. In addition, all cause 30-day hospital readmission rates were 16% in the exebacase + SOC group compared to 30.8% in the SOC only group. These results point to a pharmacoeconomic benefit in addition to the clinical efficacy that exebacase provides. We anticipate the company meeting with the FDA in the summer of 2019 to receive guidance on the Phase 3 clinical trial, which we anticipate beginning in 1H2020.

SUMMARY DATA

52-Week High	**$2.82**
52-Week Low	**$0.36**
One-Year Return (%)	**-72.93**
Beta	**-0.35**
Average Daily Volume (sh)	**419,013**
Shares Outstanding (mil)	**79**
Market Capitalization ($mil)	**$39**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**46**
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	**-3.9**
P/E using 2019 Estimate	**-1.1**

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 E	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	-$0.09 E	-$0.08 E	-$0.08 E	-$0.34 E
2020					-$0.36 E
2021					-$0.39 E

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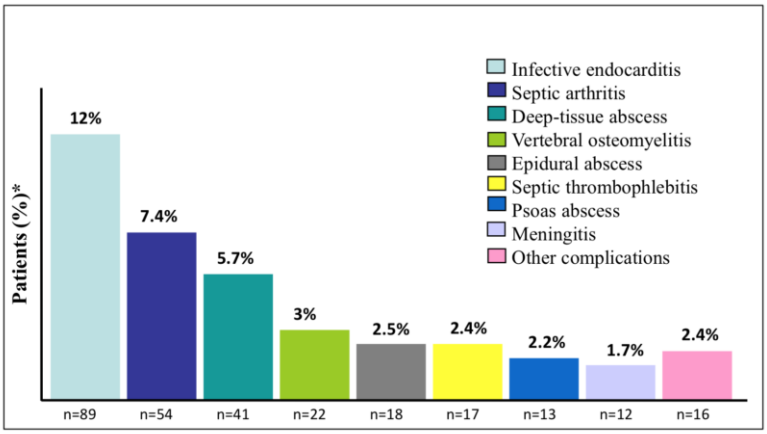
Business Update

R&D Symposium Highlights Positive Exebacase Data

On May 14, 2019, ContraFect Corp. (CFRX) held an R&D symposium on the potential for direct lytic agents (lysins and amurins) as anti-infective agents. Included in the symposium were four presentations, including a discussion of the Phase 2 clinical trial of exebacase in patients with bacteremia caused by both methicillin sensitive *Staphylococcus aureus* (MSSA) and methicillin resistant *S. aureus* (MRSA).

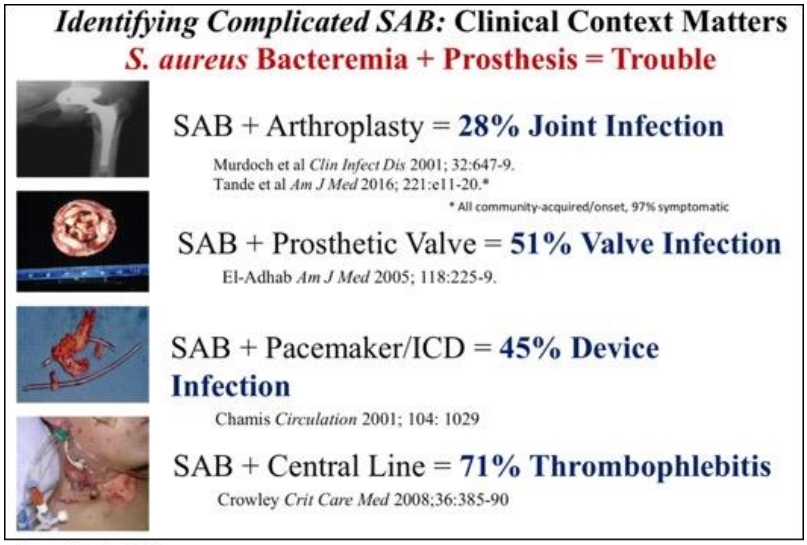
Vance Fowler, M.D. – *Staphylococcus aureus* Bacteremia: Updates and Controversies

Dr. Fowler was the Principal Investigator for the Phase 2 clinical trial of exebacase in patients with *S. aureus* bacteremia (SAB). His presentation gave an overview of SAB, including the difference between an uncomplicated or complicated infection. According to Dr. Fowler, most cases of SAB are complicated, which are much more difficult to treat than uncomplicated. Part of the reason for this is because there are so many different types of complications that are seen with SAB, as shown in the following figure.



Fowler, et al. *Arch Intern Med*. 2003;163:2066-2072.

The worst complications for SAB typically occur if the patient has a prosthesis, as biofilms are likely to form that can be very difficult to treat and typically can only be cured with surgery. The following figure shows what percentage of SAB infections lead to prosthetic infections with various types of protheses.



Source: Fowler, 2019

Dr. Fowler discussed how there is very limited high-quality clinical trial data available on SAB. However, a couple of treatment principles have emerged to help bring about the best possible outcome for patients:

1) Find the source of the infection (e.g., the abscess, the infected hardware, the infected joint)
2) Choose the correct antibiotic (MSSA = beta-lactam antibiotic, vancomycin not an optimal choice; MRSA = daptomycin and vancomycin only two FDA-approved agents, daptomycin more effective)

In closing, Dr. Fowler indicated that SAB is a very common condition and is potentially lethal due to the fact that the standard of care (SOC) is suboptimal. SOC antibiotics are not effective against biofilms, thus if one forms it typical means surgery is required (and removal of the prothesis if infected). In addition, MRSA is especially problematic as there are only two FDA-approved agents to treat it. Thus, new treatment options are desperately needed.

Cara Cassino, M.D. – Exebacase: A New Therapeutic Modality to Improve Clinical Outcomes of MRSA Bacteremia

Dr. Cassino is the Chief Medical Officer of ContraFect. She gave an overview of the data from the Phase 2 clinical trial of exebacase in SAB. We have previously discussed that data, which you can access here and here. As it relates to the issues raised by Dr. Fowler, the Phase 2 data showed exebacase was highly effective against MRSA and preclinical data has shown the ability of exebacase to eliminate biofilms.

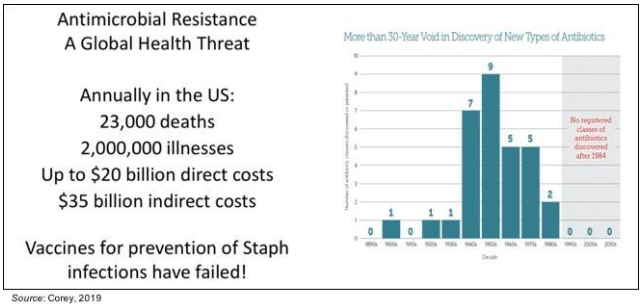
In this presentation, Dr. Cassino highlighted new data on Day 180 immunologic response. Consistent with what was seen in the Phase 1 clinical trial, 50.7% of exebacase-treated patients developed anti-drug antibodies (ADAs) in the Phase 2 trial. However, only nine of those patients developed IgE antibodies (which could be an indication of allergic hypersensitivity), and the titers were generally very low (only slightly above the limit of detection) and transient. Thus, there appears to be very little risk for an allergic response to exebacase.

Encouraging health economic data presented by Dr. Cassino showed that exebacase reduced the median number of hospital days from study drug administration to discharge. Patients in the SOC only group had a median of 10.0 hospital days while those treated with exebacase + SOC only had a median of 6.0 days. In addition, all-cause 30-day hospital readmission rates among MRSA patients were lower for those treated with exebacase (16.0% vs. 30.8% for exebacase vs. SOC only) and *S. aureus* specific 30-day hospital readmission rates were lower as well (8.0% vs 15.4% for exebacase vs SOC only). Thus, exebacase is not only showing potent clinical efficacy in MRSA patients, but appears to have a pharmacoeconomic benefit as well.

Dr. Cassino also commented on the Phase 3 program for exebacase. While the final details have yet to be confirmed since the company still needs to meet with the FDA this summer to receive the agency's input, we believe it will be very similar to the Phase 2 study. The company will conduct a single superiority design, randomized, double blind, controlled clinical trial that will take place predominantly in the U.S. The patient population will consist of those with MRSA bacteremia, including those with right-sided endocarditis. We anticipate learning additional details following the company's meeting with the FDA and we anticipate the study initiating in the first half of 2020.

G. Ralph Corey, M.D. – Exebacase: A Clinical Perspective

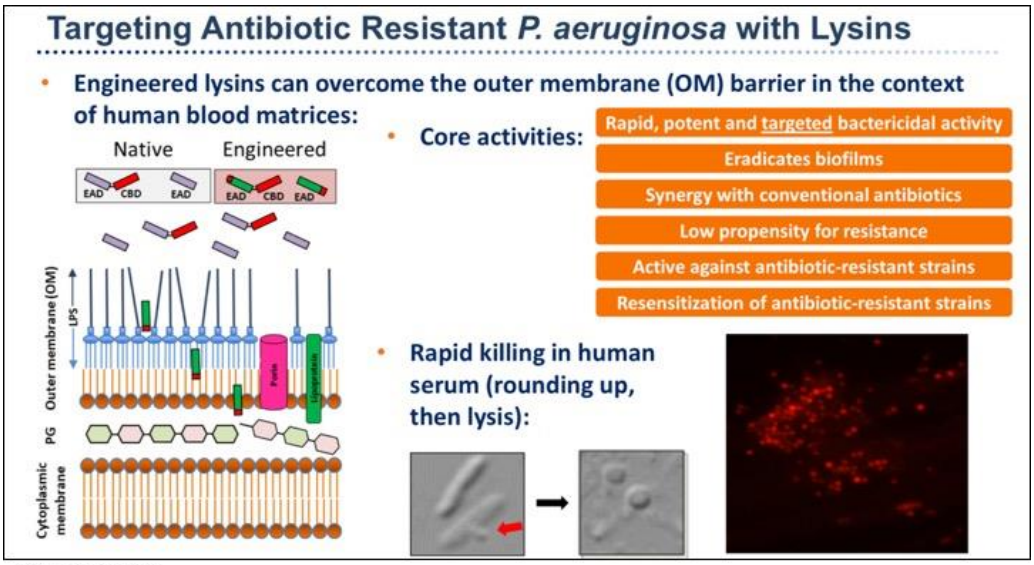
Dr. Corey is a Professor of Medicine in the Division of Infectious Diseases at Duke University. He provided an overview of the challenges in treating *S. aureus* infections (including both MSSA and MRSA) and discussed two patients that had difficult to treat *S. aureus* infections to highlight the challenges in treating the condition. He believes that exebacase could represent an entirely new treatment paradigm in SAB. Dr. Corey highlighted the fact that antibiotic resistance is continuing to increase and that there is a dearth of new types of antibiotics being discovered, thus he enthusiastically supports moving exebacase into Phase 3 testing and potentially onto the market.



Source: Corey, 2019

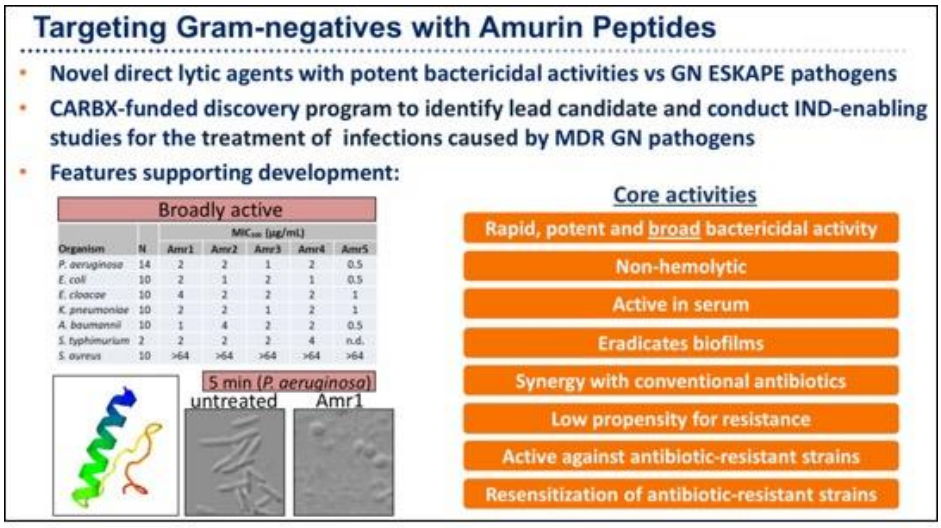
Raymond Schuch, PhD – Direct Lytic Agents

Dr. Schuch provided an overview of the development of lytic agents for the treatment of infections caused by Gram-negative pathogens, particularly those deemed the greatest public health threats such as antibiotic resistant *Pseudomonas aeruginosa*. The following slide provides an overview of the approach taken by the company to engineer a lysin capable of killing Gram-negative bacteria. It was necessary to design lysin's to target Gram-negative bacteria due to the presence of the Outer Membrane (OM), which is not seen on Gram-positive bacteria. Once past the OM, the Gram-negative lysins show similar activity to the Gram-positive lysins including rapid and potent bactericidal activity, the eradication of biofilms, and activity against antibiotic resistant organisms.



Source: Schuch, 2019

In addition to the lysins, ContraFect is also developing amurin peptides for treating Gram-negative infections. Amurins are phage-encoded lytic peptides that show activity against a broad range of Gram-negative pathogens. Like lysins, amurins have shown the ability to eradicate biofilms and work synergistically with SOC antibiotics, however unlike lysins, which show activity only against a particular species, they are broad-acting. ContraFect was recently awarded a $6.9 million grant from CARB-X to support the development of amurin drug candidates.



Source: Schuch, 2019

Financial Update

On May 10, 2019, ContraFect announced financial results for the first quarter of 2019. As expected, the company did not report any revenues for the quarter. R&D expenses for the first quarter of 2019 were $4.1 million compared

to $4.7 million for the first quarter of 2018. The decrease was primarily due to decreased spending on the Phase 2 clinical trial partially offset by increased manufacturing in preparation for a Phase 3 study of exebacase. G&A expenses were $2.3 million in the first quarter of 2019 compared to $2.2 million in the first quarter of 2018. The increase was primarily due to increased legal and intellectual property fees. The company reported net income of $11.6 million, or $0.15 per share, compared to a net loss of $19.1 million, or $0.26 per share, in the first quarter of 2018. The net income was the direct result of a $30 million, or $0.38 per share, increase in other income due to a non-cash gain from the change in the fair value of the company's warrant liabilities.

As of Mar. 31, 2019, ContraFect had cash, cash equivalents, and marketable securities of approximately $23.1 million. We estimate the company has sufficient capital to fund operations through the end of 2019. As of May 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 119.4 million shares.

Conclusion

ContraFect's R&D symposium was an excellent event and clearly showed the positive effects of exebacase treatment, particularly in patients with SAB caused by MRSA. With the Phase 3 program beginning to take shape we look forward to additional updates following the company's meeting with the FDA and at this point we continue to believe a Phase 3 trial will commence in the first half of 2020. While clearly exebacase is the main focus for the company right now, we believe the Phase 2 trial validated the entire lysin platform, for which there are a number of other development projects in the pipeline, thus making ContraFect about more than just its lead compound. Our valuation remains $4.

PROJECTED FINANCIALS

ContraFect Corp.	2018 A	Q1 A	Q2 E	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	$5.0	$5.2	$5.3	$19.6	$24.0	$28.0
General & Administrative	$8.7	$2.3	$2.2	$2.3	$2.3	$9.1	$9.5	$10.0
Other Expenses	$0	$0	$0	$0	$0	$0	$0	$0
Operating Income	($31.1)	($6.4)	($7.2)	($7.5)	($7.6)	($28.7)	($33.5)	($38.0)
Operating Margin		-	-	-	-			
Non-Operating Expenses (Net)	($6.6)	$17.9	$0.0	$0.0	$0.0	$17.9	$0.0	$0.0
Pre-Tax Income	($37.7)	$11.6	($7.2)	($7.5)	($7.6)	($10.8)	($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**	**($7.2)**	**($7.5)**	**($7.6)**	**($10.8)**	**($33.5)**	**($38.0)**
Net Margin		-	-	-	-			
Reported EPS	**($0.50)**	**$0.15**	**($0.09)**	**($0.08)**	**($0.08)**	**($0.13)**	**($0.36)**	**($0.39)**
YOY Growth		-	-	-	-			
Basic Shares Outstanding	76.1	79.4	80.0	90.0	91.0	85.1	92.0	98.0

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

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