Zacks Small-Cap Research

Sponsored - Impartial - Comprehensive

May 26, 2022 David Bautz, PhD 312-265-9471 <u>dbautz@zac</u>ks.com

Above Avg.

Med-Drugs

(Dec)

-\$0.55 A

-\$1.48 E

-\$1.33 E

-\$1.14 E

Small-Growth

scr.zacks.com

10 S. Riverside Plaza, Chicago, IL 60606

ContraFect Corp.

CFRX: Results from Interim Futility Analysis in July 2022...

Based on our updated probability adjusted DCF model that takes into account potential future revenues from CF-301 in bacteremia along with the lysin pipeline, our valuation of CFRX is \$23/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 (05/26/22) \$3.24 **Valuation** \$23.00

¢1 50

(CFRX-NASDAQ)

OUTLOOK

Risk Level

Industry

Type of Stock

(Mar)

-\$0.18 A

-\$0.51 A

2021

2022

2023

2024

(Jun)

-\$0.14 A

-\$0.31 E

On May 16, 2022, ContraFect Corp. (CFRX) announced financial results for the first quarter of 2022 and provided a business update. The company announced that the Phase 3 DISRUPT trial has eclipsed the enrollment threshold needed for the interim futility analysis by the Data Safety Monitoring Board (DSMB). This analysis will include the probability for exebacase to achieve superiority on the primary efficacy endpoint. We anticipate results in July 2022. The company recently presented multiple posters at the 32nd ECCMID Annual Meeting on CF-370, a lysin that targets Gram positive pathogens, that included *in vivo* efficacy in a rabbit acute pneumonia model along with its susceptibility profile.

SUMMARY DATA

52-Week High

52-week High	\$4.58
52-Week Low	\$2.26
One-Year Return (%)	-17.56
Beta	0.50
Average Daily Volume (sh)	117,947
Shares Outstanding (mil)	39
Market Capitalization (\$mil)	\$127
Short Interest Ratio (days)	N/A
Institutional Ownership (%)	59
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	-2.5
•	-2.7
P/E using 2020 Estimate	-2.1

iiidu	isti y			I.	(Dec) 0 A					
ZACKS ESTIMATES										
Revenu (in millions										
`	Q1	Q2	Q3	Q4	Year					
	(Mar)	(Jun)	(Sep)	(Dec)	(Dec)					
2021	0 A	0 A	0 A	0 A	0 A					
2022	0 A	0 E	0 E	0 E	0 E					
2023					0 E					
2024					0 E					
Earning	gs per Sh	are								
	Q1	Q2	Q3	Q4	Year					

(Sep)

-\$0.13 A

-\$0.32 E

(Dec)

-\$0.11 A

-\$0.34 E

WHAT'S NEW

Business Update

Update on Phase 3 DISRUPT Trial

ContraFect, Corp. (CFRX) is currently conducting the Phase 3 DISRUPT (Direct Lysis of *Staph aureus* Resistant Pathogen Trial) trial of exebacase in patients with *Staphylococcus aureus* bacteremia, including right-sided endocarditis. The DISRUPT trial is a randomized, double blind, placebo controlled study being conducted at over 40 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.

The company recently announced that the DISRUPT trial has passed the enrollment threshold necessary for the interim futility analysis. The trial has currently approximately two-thirds of the entire study population enrolled. The interim futility analysis will be conducted by the Data Safety Monitoring Board (DSMB) and will include an assessment of the probability for exebacase to achieve superiority on the primary efficacy endpoint. We anticipate the results of the interim futility analysis in July 2022.

The primary endpoint of the trial is 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.

In March 2021, ContraFect announced an \$86.8 million contract with the Biomedical Advanced Research and Development Authority (BARDA) to support the DISRUPT trial. The company received an initial tranche of \$9.8 million with up to \$77.0 million in future support being dependent on progress and clinical success in the DISRUPT trial. Following completion of the trial, and assuming a positive outcome, the BARDA funding can be used to support additional development work that may be necessary for FDA approval, including manufacturing and regulatory activities. It could also cover any post-approval commitments, such as the completion of the pediatric study.

Multiple Presentations on CF-370 at ECCMID

In April 2022, ContraFect announced multiple presentations on CF-370 at the 32nd European Congress of Clinical Microbiology & Infectious Diseases (ECCMID) Annual Meeting, which included its activity in an *in vivo* model and *in vitro* analysis of its susceptibility to resistance.

In vivo efficacy of CF-370 alone and in addition to amikacin in the rabbit acute pneumonia model caused by an extensively drug-resistant (XDR) *Pseudomonas aeruginosa*, AR-769

This study utilized a rabbit model of pulmonary infection induced by *Pseudomonas aeruginosa* and examined two doses of CF-370 (3 and 10 mg/kg, iv, single dose), two doses of CF-370 (3 and 10 mg/kg, iv, single dose) in combination with amikacin (4 mg/kg, iv, 3 doses every 8 hours), amikacin alone, vehicle control, and an untreated cohort. Results showed that CF-370, when administered alone and in combination with amikacin, significantly reduced bacterial counts by approximately 3.0 log₁₀ cfu/g tissue when compared to amikacin alone (P≤0.0004) and by approximately 4.5 log₁₀ cfu/g tissue when compared to vehicle control . In addition, significantly reduced bacterial counts were seen in secondary organs of interest (spleen and kidney) when CF-370 was administered in combination with amikacin compared to amikacin alone.

Lysin CF-370 exhibits a low propensity for decreased susceptibility in Gram-negative (GN) ESKAPE pathogens

This study utilized the standard 28-day serial passage method to induce *in vitro* resistance against CF-370, ciprofloxacin, and levofloxacin. CF-370 had an extremely low propensity for developing decreased susceptibility to the Gram negative ESKAPE pathogens (*P. aeruginosa*, *Acinetobacter baumannii*, *Klebsiella pneumoniae*, and *Enterobacter cloacae*) and *Escherichia coli*. Minimum inhibitory concentrations (MICs) for CF-370 did not change against any of the pathogens, except for a 2-fold increase with *E. cloacae*. In contrast, MIC increases ranged from 32-fold to 512-fold for levofloxacin and ciprofloxacin.

Lysin CF-370 suppresses in vitro resistance in *Pseudomonas aeruginosa* to meropenem, tobramycin and levofloxacin

This study utilized the 28-day serial passage method to test whether CF-370 could suppress in vitro resistance in *P. aeruginosa* to current standard of care antibiotics (meropenem, tobramycin, and levofloxacin). The addition of CF-370 at only 1/8x MIC completely repressed resistance of *P. aeruginosa* to both tobramycin and levofloxacin and increased only 2-fold to meropenem, compared to 4-fold, 16-fold, and 32-fold MIC changes without CF-370, respectively.

Financial Update

On May 16, 2022, ContraFect <u>announced</u> financial results for the first quarter of 2022. As expected, the company did not report any revenues for the three months ending March 31, 2022. Net loss for the first quarter of 2022 was \$20.2 million, or \$0.51 per share, compared to a net loss of \$5.2 million, or \$0.18 per share, for the first quarter of 2021. R&D expenses for the first quarter of 2022 were \$12.7 million, compared to \$8.0 million for the first quarter of 2021. The increase was primarily due to an increase in spending on manufacturing costs that will support a potential BLA submission and clinical activities associated with the Phase 3 DISRUPT trial. G&A expenses for the first quarter of 2022 were \$3.3 million, compared to \$2.8 million for the first quarter of 2021. The increase was primarily due to increased personnel and related expenses.

As of March 31, 2022, ContraFect had approximately \$42.3 million in cash, cash equivalents, and marketable securities. As of May 10, 2022, the company had approximately 39.3 million shares outstanding and, when factoring stock options and warrants, a fully diluted share count of approximately 54.4 million.

Conclusion

We are anxiously awaiting the results of the planned interim futility analysis for the Phase 3 DISRUPT trial, which we now expect in July 2022. The data presented at ECCMID for CF-370 is very encouraging and we will be following its development very closely, with IND-enabling activities currently ongoing. As we await the results of the interim futility analysis we have made no changes to our model and our valuation remains at \$23 per share.

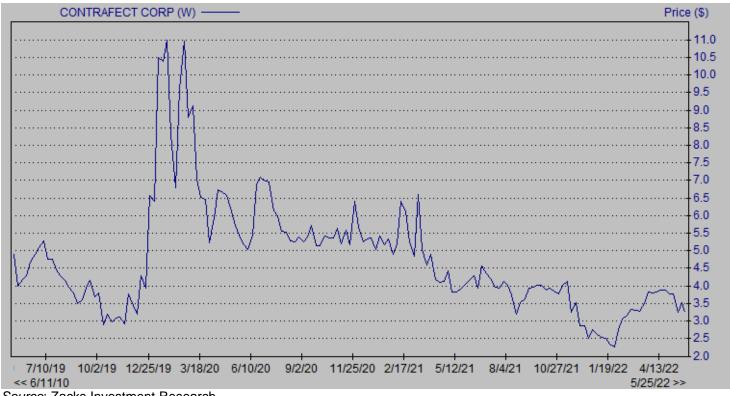
PROJECTED FINANCIALS

ContraFect Corp.	2021 A	Q1 A	Q2 E	Q3 E	Q4 E	2022 E	2023 E	2024 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	\$35.5	\$12.7	\$9.2	\$9.5	\$10.0	\$41.4	\$40.0	\$42.0
General & Administrative	\$11.8	\$3.3	\$3.1	\$3.1	\$3.2	\$12.7	\$13.0	\$15.0
Other Expenses	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Operating Income	(\$47.3)	(\$16.0)	(\$12.3)	(\$12.6)	(\$13.2)	(\$54.1)	(\$53.0)	(\$57.0)
Operating Margin		-	-	-	-			
Non-Operating Expenses (Net)	\$27.0	(\$4.2)	\$0.0	\$0.0	\$0.0	(\$4.2)	\$0.0	\$0.0
Pre-Tax Income	(\$20.3)	(\$20.2)	(\$12.3)	(\$12.6)	(\$13.2)	(\$58.3)	(\$53.0)	(\$57.0)
Income Taxes Paid	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Tax Rate	0%	0%	0%	0%	0%	0%	0%	0%
Net Income	(\$20.3)	(\$20.2)	(\$12.3)	(\$12.6)	(\$13.2)	(\$58.3)	(\$53.0)	(\$57.0)
Net Margin		-	-	-	-			
Reported EPS	(\$0.55)	(\$0.51)	(\$0.31)	(\$0.32)	(\$0.34)	(\$1.48)	(\$1.33)	(\$1.14)
YOY Growth		-	-	-	-			
Basic Shares Outstanding	36.8	39.3	39.3	39.3	39.3	39.3	40.0	50.0

Source: Zacks Investment Research, Inc.

David Bautz, PhD

HISTORICAL STOCK PRICE



Source: Zacks Investment Research

DISCLOSURES

The following disclosures relate to relationships between Zacks Small-Cap Research ("Zacks SCR"), a division of Zacks Investment Research ("ZIR"), and the issuers covered by the Zacks SCR Analysts in the Small-Cap Universe.

ANALYST DISCLOSURES

I, David Bautz, PhD, hereby certify that the view expressed in this research report accurately reflect my personal views about the subject securities and issuers. I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the recommendations or views expressed in this research report. I believe the information used for the creation of this report has been obtained from sources I considered to be reliable, but I can neither guarantee nor represent the completeness or accuracy of the information herewith. Such information and the opinions expressed are subject to change without notice.

INVESTMENT BANKING AND FEES FOR SERVICES

Zacks SCR does not provide investment banking services nor has it received compensation for investment banking services from the issuers of the securities covered in this report or article.

Zacks SCR has received compensation from the issuer directly, from an investment manager, or from an investor relations consulting firm engaged by the issuer for providing non-investment banking services to this issuer and expects to receive additional compensation for such non-investment banking services provided to this issuer. The non-investment banking services provided to the issuer includes the preparation of this report, investor relations services, investment software, financial database analysis, organization of non-deal road shows, and attendance fees for conferences sponsored or co-sponsored by Zacks SCR. The fees for these services vary on a per-client basis and are subject to the number and types of services contracted. Fees typically range between ten thousand and fifty thousand dollars per annum. Details of fees paid by this issuer are available upon request.

POLICY DISCLOSURES

This report provides an objective valuation of the issuer today and expected valuations of the issuer at various future dates based on applying standard investment valuation methodologies to the revenue and EPS forecasts made by the SCR Analyst of the issuer's business. SCR Analysts are restricted from holding or trading securities in the issuers that they cover. ZIR and Zacks SCR do not make a market in any security followed by SCR nor do they act as dealers in these securities. Each Zacks SCR Analyst has full discretion over the valuation of the issuer included in this report based on his or her own due diligence. SCR Analysts are paid based on the number of companies they cover. SCR Analyst compensation is not, was not, nor will be, directly or indirectly, related to the specific valuations or views expressed in any report or article.

ADDITIONAL INFORMATION

Additional information is available upon request. Zacks SCR reports and articles are based on data obtained from sources that it believes to be reliable, but are not guaranteed to be accurate nor do they purport to be complete. Because of individual financial or investment objectives and/or financial circumstances, this report or article should not be construed as advice designed to meet the particular investment needs of any investor. Investing involves risk. Any opinions expressed by Zacks SCR Analysts are subject to change without notice. Reports or articles or tweets are not to be construed as an offer or solicitation of an offer to buy or sell the securities herein mentioned.

CANADIAN COVERAGE

This research report is a product of Zacks SCR and prepared by a research analyst who is employed by or is a consultant to Zacks SCR. The research analyst preparing the research report is resident outside of Canada, and is not an associated person of any Canadian registered adviser and/or dealer. Therefore, the analyst is not subject to supervision by a Canadian registered adviser and/or dealer, and is not required to satisfy the regulatory licensing requirements of any Canadian provincial securities regulators, the Investment Industry Regulatory Organization of Canada and is not required to otherwise comply with Canadian rules or regulations.