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August 17, 2023
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ContraFect Corp. (CFRX-NASDAQ)

CFRX: CF-370 IND to be Filed in 3Q23…

Based on our updated probability adjusted DCF model that takes into account potential future revenues from the lysin pipeline, our valuation of CFRX is $7.00/share. This model is highly dependent upon clinical success for exebacase and advancement of additional lysin products and will be adjusted accordingly based upon future clinical results.

Current Price (08/17/23)	$0.91
Valuation	**$7.00**

OUTLOOK

On August 14, 2023, ContraFect Corp. (CFRX) announced financial results for the second quarter of 2023 and provided a business update. The company is set to file the Investigational New Drug (IND) application with the FDA in the third quarter of 2023 for CF-370, the company lead development lysin that targets Gram-negative bacteria, including *Pseudomonas aeruginosa*, the most common pathogen isolated from adults with Cystic Fibrosis (CF). Following acceptance of the IND, a Phase 1 program will be initiated for CF-370 that will investigate single- and multiple-doses in healthy volunteers to evaluate safety and tolerability. A planned Phase 2 proof-of-concept study may evaluate the efficacy of CF-370 in CF patients.

SUMMARY DATA

52-Week High	**$26.64**
52-Week Low	**$0.90**
One-Year Return (%)	**-96.40**
Beta	**0.46**
Average Daily Volume (sh)	**40,967**
Shares Outstanding (mil)	**2**
Market Capitalization ($mil)	**$1**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**14**
Insider Ownership (%)	**2**
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	**N/A**
P/E using 2020 Estimate	**N/A**

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

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2022	0 A	0 A	0 A	0 A	0 A
2023	0 A	0 A	0 E	0 E	0 E
2024					0 E
2025					0 E

Earnings per Share

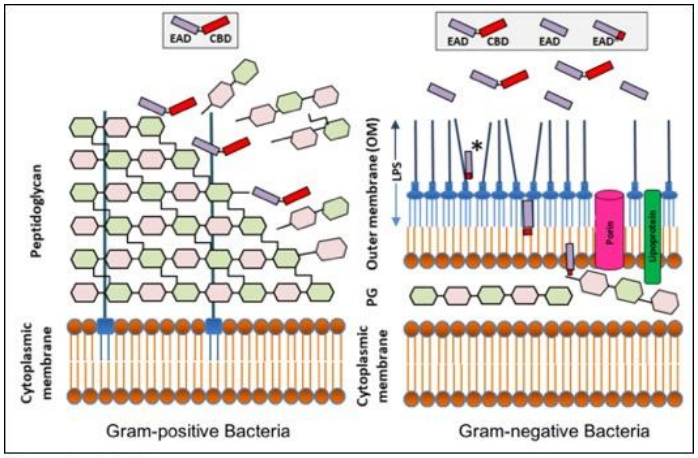
	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2022	-$41.00 A	-$36.79 A	-$34.71 A	-$16.12 A	-$124.97 A
2023	-$0.69 A	-$1.94 A	-$0.66 E	-$0.69 E	-$3.44 E
2024					-$1.50 E
2025					-$1.11 E

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Business Update

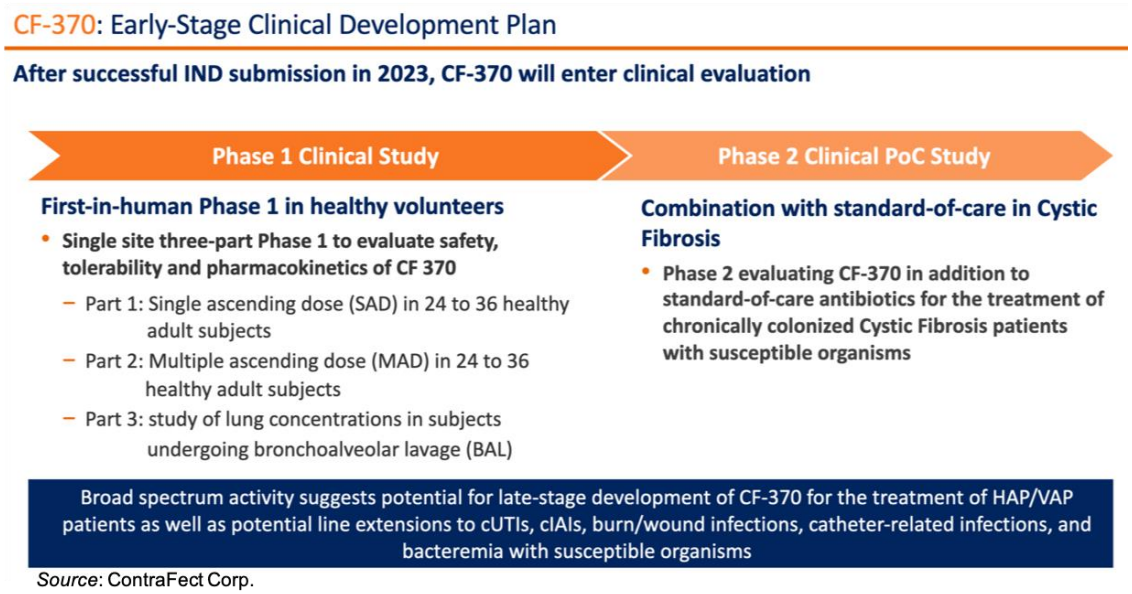
Update on CF-370

CF-370 is the company's lead engineered lysin development candidate targeting 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.

The following slide gives an overview of the planned early stage clinical trials for CF-370 following submission of the IND, which we expect to occur in the third quarter of 2023. While a Phase 2 proof-of-concept trial is currently planned in patients with cystic fibrosis, the broad spectrum activity of CF-370 means it could likely be used for treating various types of infectionis, including pneumonia, urinary tract infections, wound infections, and bacteremia caused by susceptible organisms.



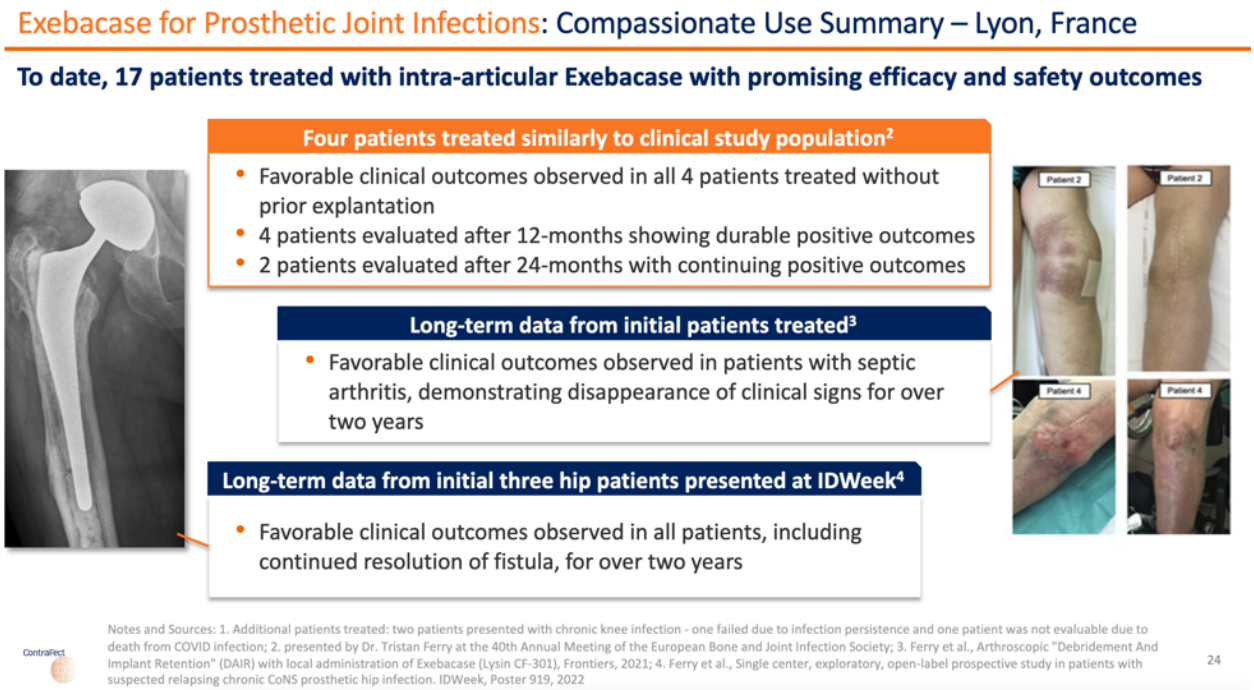
Source: ContraFect Corp.

Phase 1b/2 Trial for Exebacase in Chronic Knee Prosthetic Joint Infections Continuing Enrollment

In April 2023, ContraFect Corp. (CFRX) announced the first patient had been dosed in the Phase 1b/2 clinical trial of exebacase in the setting of a minimally-invasive arthroscopic debridement, antibiotics, irrigation, and retention (DAIR) procedure in patients with chronic prosthetic joint infection (PJI) of the knee due to *Staphylococcus aureus* or Coagulase-Negative Staphylococci (CoNS).

The trial is a randomized, double blind, placebo controlled two-part study of exebacase to assess its safety and efficacy. Part I of the study will evaluate the safety, pharmacokinetics (PK), clinical outcomes, and microbiologic response in patients through Day 42. The study allows for up to two doses of intra-articularly administered exebacase in addition to systemic antibiotics in up to two patient cohorts. Part II of the trial will be a long-term follow-up study of safety and efficacy parameters in patients who complete Part 1 of the trial. The follow-up assessments will be performed on Days 90, 180, 360, and 720.

The following slide gives a summary of the compassionate use data for exebacase for prosthetic joint infections. One cohort of four patients were treated similarly to the clinical study population. Favorable outcomes were noted for all four patients, with two of the patients having a 24-month follow up with continued positive outcomes. Three hip replacement patients were included in a separate study and all had previous iterative hip prosthesis exchange, a high total number of surgeries (6-10), and recent persistent or intermittent fistula. At two years follow up, all patients had resolution of fistula and no clinical signs of infection on suppressive antimicrobial therapy.



Source: ContraFect Corp.

PJI carry a high economic burden. Of the approximately 1.5 million hip and knee joint arthroplasties performed in the U.S. each year, approximately 2% will be associated with a concurrent infection. The rate of arthroplasties is estimated to at least double by the year 2030, thus representing approximately 65,000 cases of knee and hip infections in that year. Unfortunately, antibiotic treatment alone is typically unsuccessful due to the formation of biofilms in the joint, thus necessitating a two-stage revision (joint removal, antibiotics, then joint replacement), which is both costly and debilitating. The costs to U.S. hospitals in the year 2030 for prosthetic joint infections is estimated to be approximately $1.8 billion (Premkumar *et al*., 2021).

Financial Update

On August 14, 2023, ContraFect announced financial results for the second quarter of 2023. As expected, the company did not report any revenues for the three months ending June 30, 2023. Net loss for the second quarter of 2023 was $7.6 million, or $1.94 per share, compared to a net loss of $18.1 million, or $36.79 per share, for the

second quarter of 2022. R&D expenses for the second quarter of 2023 were $4.9 million, compared to $16.8 million for the second quarter of 2022. The decrease was primarily due to significantly reduced expenditures on late-stage development activities to support the continued closure of the Phase 3 DISRUPT trial, CMC activities for exebacase, external clinical consultants, and headcount as a result of restructuring. G&A expenses for the second quarter of 2023 were $3.1 million, compared to $3.3 million for the second quarter of 2022. The decrease was primarily due to a decrease in personnel costs and related expenses.

As of June 30, 2023, ContraFect had approximately $14.4 million in cash and cash equivalents. In June 2023, the company entered into a warrant exercise agreement with an existing accredited investor to exercise certain outstanding warrants to purchase an aggregate of 7.0 million shares of the company's stock. In consideration, the exercising holder received new unregistered warrants to purchase an aggregate of 7.0 million shares, each with an exercise price of $1.36 and an expiration date five years from issuance. Gross proceeds from the transaction were approximately $9.6 million. As of August 10, 2023, the company had approximately 10.7 million shares outstanding and, when factoring stock options and warrants, a fully diluted share count of approximately 10.8 million.

Conclusion

We anticipate the IND for CF-370 being filed in the third quarter of 2023 and we look forward to clinical trials initiating shortly thereafter. Exebacase has been successful in the compassionate use setting for treating PJIs, and we look forward to additional updates from the company as that study continues enrolling patients. We have made no changes to our model and our valuation remains at $7.00 per share.

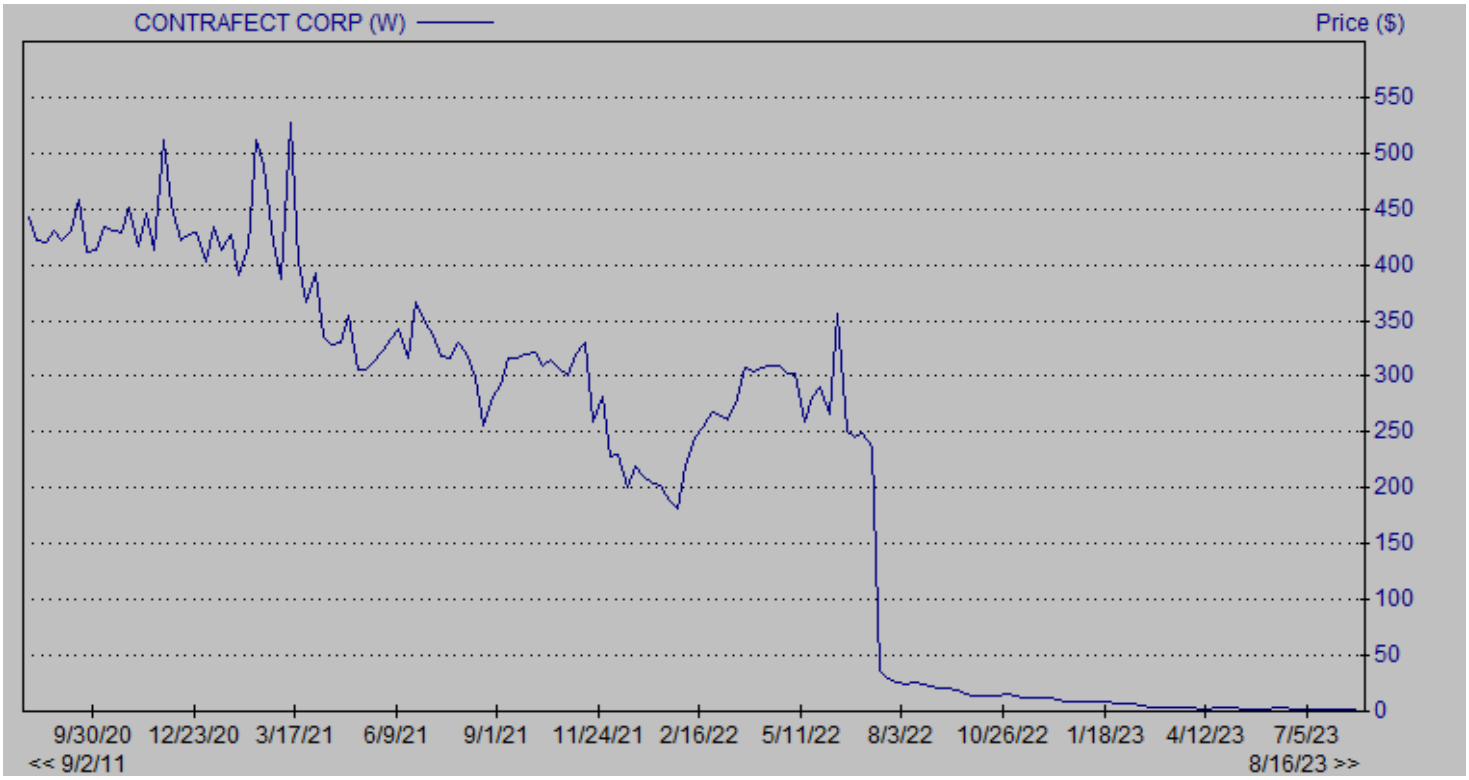
PROJECTED FINANCIALS

ContraFect Corp.	2022 A	Q1 A	Q2 A	Q3 E	Q4 E	2023 E	2024 E	2025 E
Exebacase	$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	$44.7	$5.3	$4.9	$4.7	$5.0	$19.9	$20.0	$23.0
General & Administrative	$12.2	$3.6	$3.1	$2.4	$2.4	$11.5	$10.0	$10.4
Other Expenses	$8	$0	$0	$0	$0	$0	$0	$0
Operating Income	($64.6)	($8.9)	($8.0)	($7.1)	($7.4)	($31.3)	($30.0)	($33.4)
Operating Margin		-	-	-	-			
Non-Operating Expenses (Net)	($0.5)	$7.5	$0.4	$0.0	$0.0	$7.9	$0.0	$0.0
Pre-Tax Income	($65.2)	($1.4)	($7.6)	($7.1)	($7.4)	($23.4)	($30.0)	($33.4)
Income Taxes Paid	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	**($65.2)**	**($1.4)**	**($7.6)**	**($7.1)**	**($7.4)**	**($23.4)**	**($30.0)**	**($33.4)**
Net Margin		-	-	-	-			
Reported EPS	**($124.97)**	**($0.69)**	**($1.94)**	**($0.66)**	**($0.69)**	**($3.44)**	**($1.50)**	**($1.11)**
YOY Growth		-	-	-	-			
Basic Shares Outstanding	0.5	2.0	3.9	10.7	10.7	6.8	20.0	30.0

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

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