Zacks Small-Cap Research
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Virios Therapeutics, Inc. (VIRI-NASDAQ)

VIRI: FORTRESS Trial Does Not Meet Primary Efficacy Endpoint…

Based on our probability adjusted DCF model that takes into account potential future revenues of IMC-1, VIRI is valued at $7.00/share. This model is highly dependent upon continued clinical success of IMC-1 and will be adjusted accordingly based on future clinical results.

Current Price (09/19/22)	$8.77
Valuation	**$7.00**

OUTLOOK

On September 19, 2022, Virios Therapeutics, Inc. (VIRI) announced topline results for the Phase 2b FORTRESS trial of IMC-1 for the treatment of fibromyalgia (FM). The company reported that the study did not achieve statistical significance on the prespecified primary efficacy endpoint of change from baseline to Week 14 in the weekly average of daily self-reported average pain severity scores comparing IMC-1 to placebo (*P*=0.302). However, a deeper look at the data showed a potential treatment response based on the timing of patient enrollment. Patients enrolled during the first half of the trial (June 2021 – November 2021) showed no treatment effect for IMC-1, while patients enrolled in the second half of the trial (November 2021 – April 2022) showed a statistically significant improvement on the primary endpoint (*P*=0.03) as well as key secondary endpoints. The company will continue to analyze the FORTRESS data and we anticipate an update on the development of IMC-1 when that analysis is concluded.

SUMMARY DATA

52-Week High	**$8.77**
52-Week Low	**$3.31**
One-Year Return (%)	**70.96**
Beta	**0.63**
Average Daily Volume (sh)	**24,712**
Shares Outstanding (mil)	**8**
Market Capitalization ($mil)	**$73**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**14**
Insider Ownership (%)	**20**
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 2021 Estimate	**N/A**
P/E using 2022 Estimate	**N/A**

Risk Level	**High**
Type of Stock	**N/A**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(In millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2021	0 A	0 A	0 A	0 A	0 A
2022	0 A	0 A	0 E	0 E	0 E
2023					0 E
2024					0 E

Earnings per Share

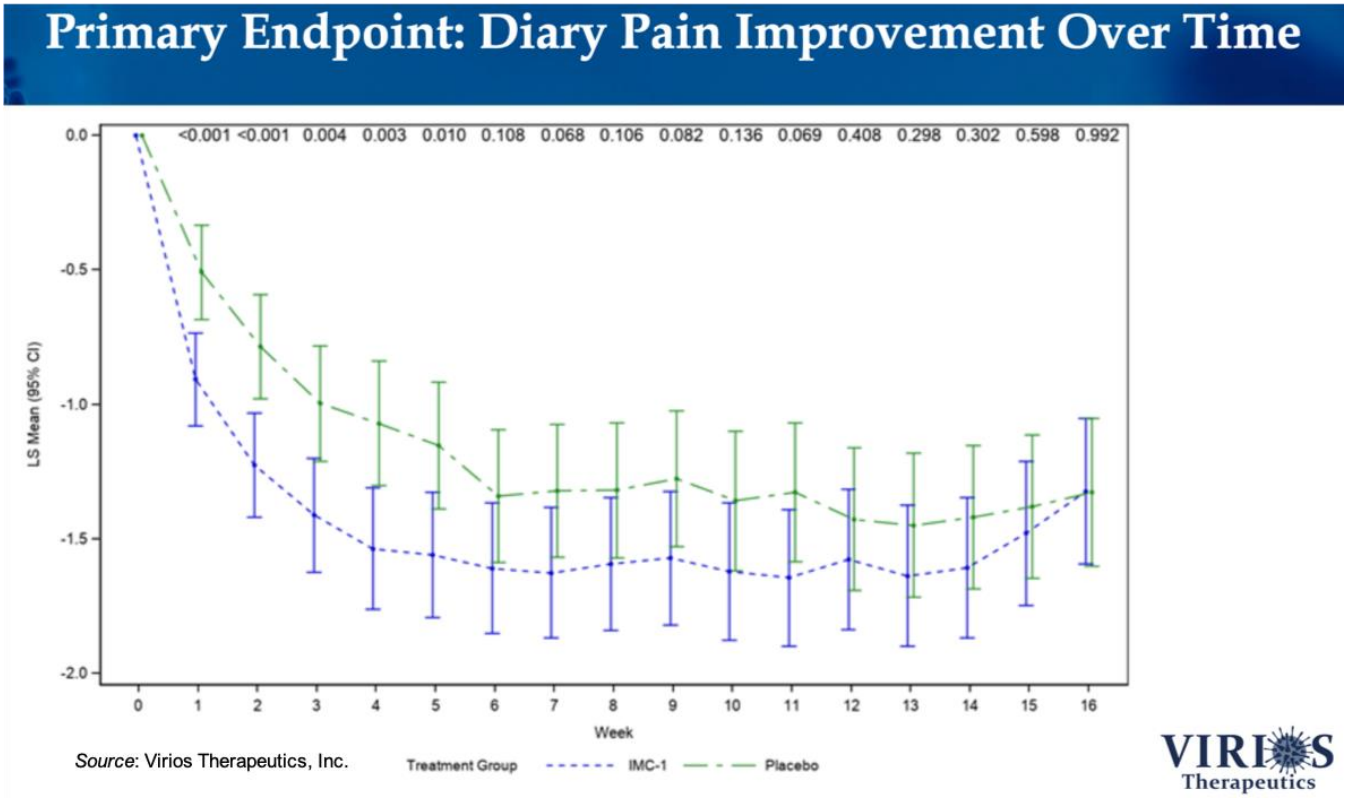
	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2021	-$0.37 A	-$0.51 A	-$0.49 A	-$0.54 A	-$1.92 A
2022	-$0.48 A	-$0.44 A	-$0.52 E	-$0.51 E	-$1.94 E
2023					-$1.94 E
2024					-$2.16 E

Business Update

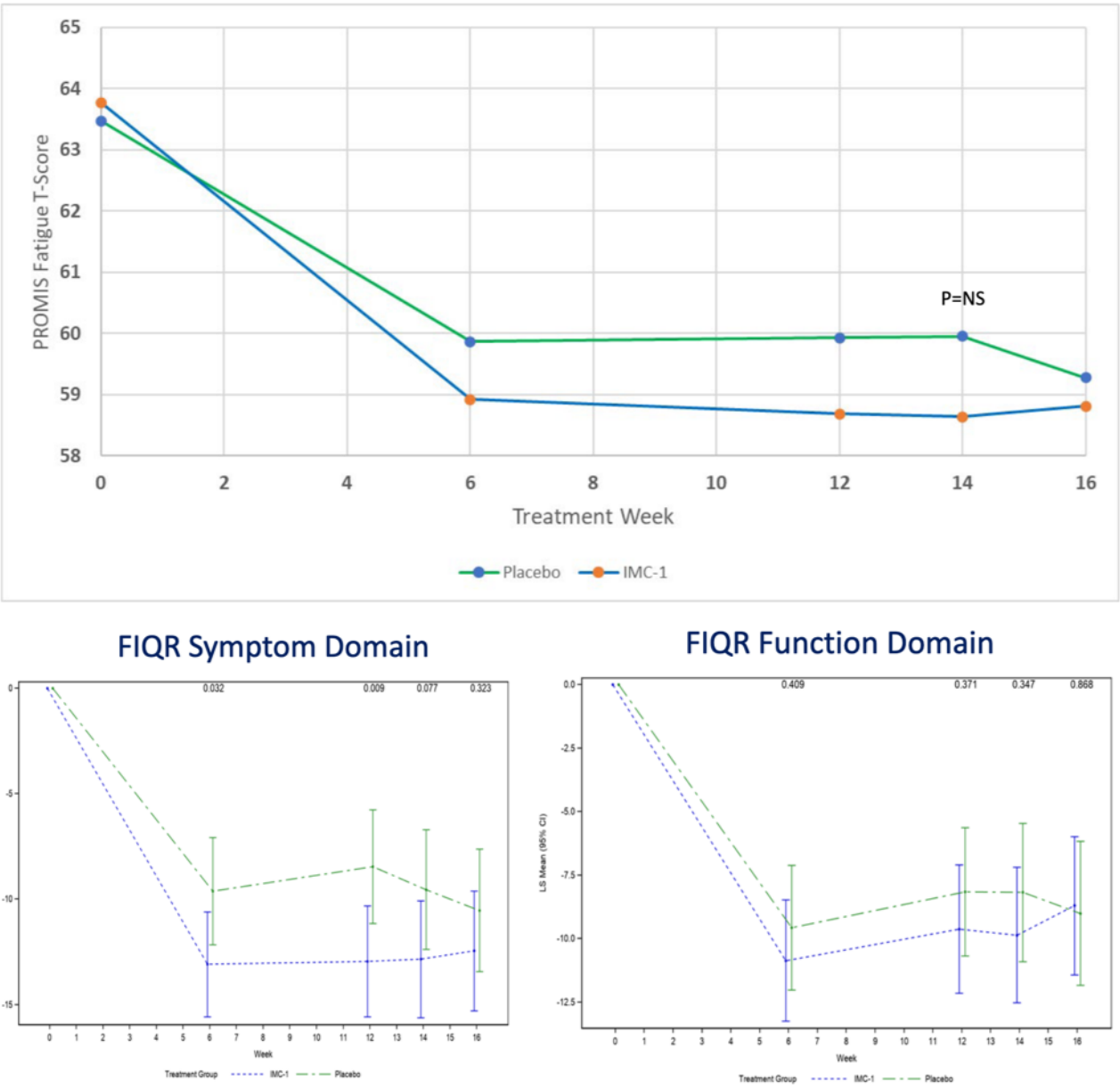
FORTRESS Trial Does Not Meet Primary Endpoint

On September 19, 2022, Virios Therapeutics, Inc. (VIRI) announced topline results from the Phase 2b FORTRESS (Fibromyalgia Outcome Research Trial Evaluating Synergistic Suppression of Herpes Simplex Virus-1) trial of IMC-1 for the treatment of fibromyalgia (FM). The FORTRESS trial was a randomized double blind, placebo controlled study of IMC-1. The primary endpoint of the trial was reduction in pain and secondary endpoints included change in fatigue, sleep disturbance, global health status, and patient functionality (NCT04748705). A copy of the company's data presentation can be found here.

The topline results showed that the FORTRESS trial did not achieve statistical significance on the prespecified primary efficacy endpoint of change from baseline to Week 14 in the weekly average of daily self-reported average pain severity scores comparing IMC-1 to placebo (*P*=0.302). The following graph shows the primary endpoint over the 16 weeks of the trial (all participants received placebo after Week 14). Patients receiving IMC-1 showed a statistically significant treatment effect over the first five weeks of the trial, however that separation diminished between the two treatment groups and by Week 14 there was no statistically significant difference.



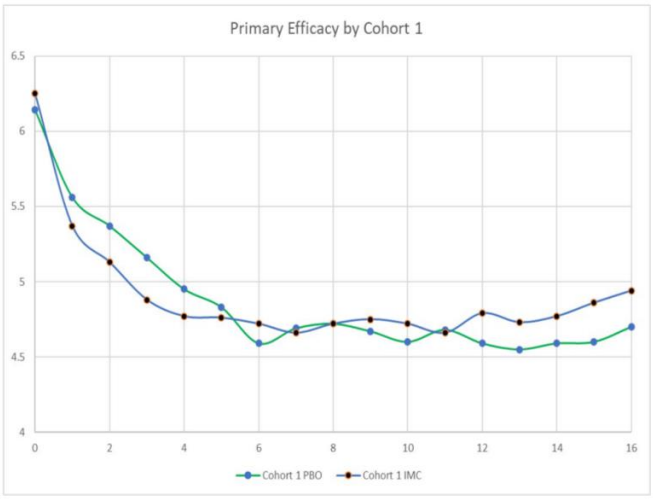
A similar lack of separation between the two treatment groups was seen in the secondary endpoints examining the PROMIS Fatigue outcome as well as the FIQR Symptom Domain and the FIQR Function Domain, as shown in the following graphs.

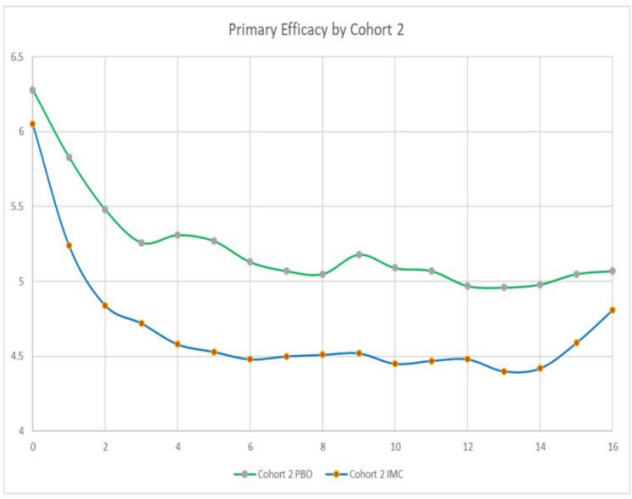


Source: Virios Therapeutics, Inc.

The company performed an initial deeper examination of the data by separating out patients that were enrolled in the first half of the trial ("Cohort 1") compared to patients that were enrolled in the second half of the trial ("Cohort 2"). It was noted that during the first half of the trial the Delta variant of SARS-CoV-2 was the predominant strain circulating in the U.S. while during the second half of the trial the Omicron strain was dominant. While the differing SARS-CoV-2 strains may not have impacted the FORTRESS trial, it is interesting that there seems to be a large difference in the efficacy outcomes for the two cohorts.

The following graphs show the primary efficacy daily pain score outcomes for Cohort 1 and Cohort 2. For Cohort 1, there was no statistically significant difference between the two treatment groups (*P*=-0.484). However, for Cohort 2 there was a statistically significant difference that favored IMC-1 treatment (*P*=0.030). This statistically significant difference was seen not just for the primary outcome but in the PROMIS Fatigue, FIQR Symptom Domain, and the mean change in HADS Depression Score, suggesting that those results may not just be a statistical artifact.





Source: Virios Therapeutics, Inc.

Importantly, IMC-1 was well tolerated during the trial. The following table shows adverse events that were reported in >2% of IMC-1 patients. COVID-19 infection was the most reported adverse event. This was self-reported by the patient as there was no official COVID-19 testing of participants in the FORTRESS trial. Interestingly, a higher percentage of patients discontinued from the trial due to adverse events in the placebo group (8.1%) than in the IMC group (4.6%).

AEs in >2% of IMC-1 Patients	Placebo	IMC-1	Total
Preferred Term	(N=208)	(N=216)	(N=424)*
	110 (52.9%)	121 (56.0%)	231 (54.5%)
COVID-19	17 (8.2%)	20 (9.3%)	37 (8.7%)
Nausea	4 (1.9%)	8 (3.7%)	12 (2.8%)
Headache	12 (5.8%)	8 (3.7%)	20 (4.7%)
Sinusitis	7 (3.4%)	7 (3.2%)	14 (3.3%)
Upper respiratory tract infection	1 (0.5%)	7 (3.2%)	8 (1.9%)
Urinary tract infection	10 (4.8%)	7 (3.2%)	17 (4.0%)
Diarrhoea	7 (3.4%)	7 (3.2%)	14 (3.3%)
Dyspepsia	3 (1.4%)	5 (2.3%)	8 (1.9%)
Depression	2 (1.0%)	5 (2.3%)	7 (1.7%)

Source: Virios Therapeutics, Inc.

* Note: safety population was n=424 due to one patient who was randomized but never received drug

Conclusion

We were disappointed and surprised to see that the FORTRESS trial did not meet the primary efficacy endpoint, as the company's Phase 2a data showed a clear treatment effect for IMC-1 in FM patients. The company will continue to analyze the data in an effort to determine why the trial was unsuccessful and we anticipate an update on the development of IMC-1 when that analysis is complete. The initial examination of the trial data based on enrollment date is interesting, however at this point the presence of differing SARS-CoV-2 strains to explain the difference in outcome between patients enrolled in the first versus the second half of the trial is speculative and additional analysis will need to be conducted to better understand that phenomenon.

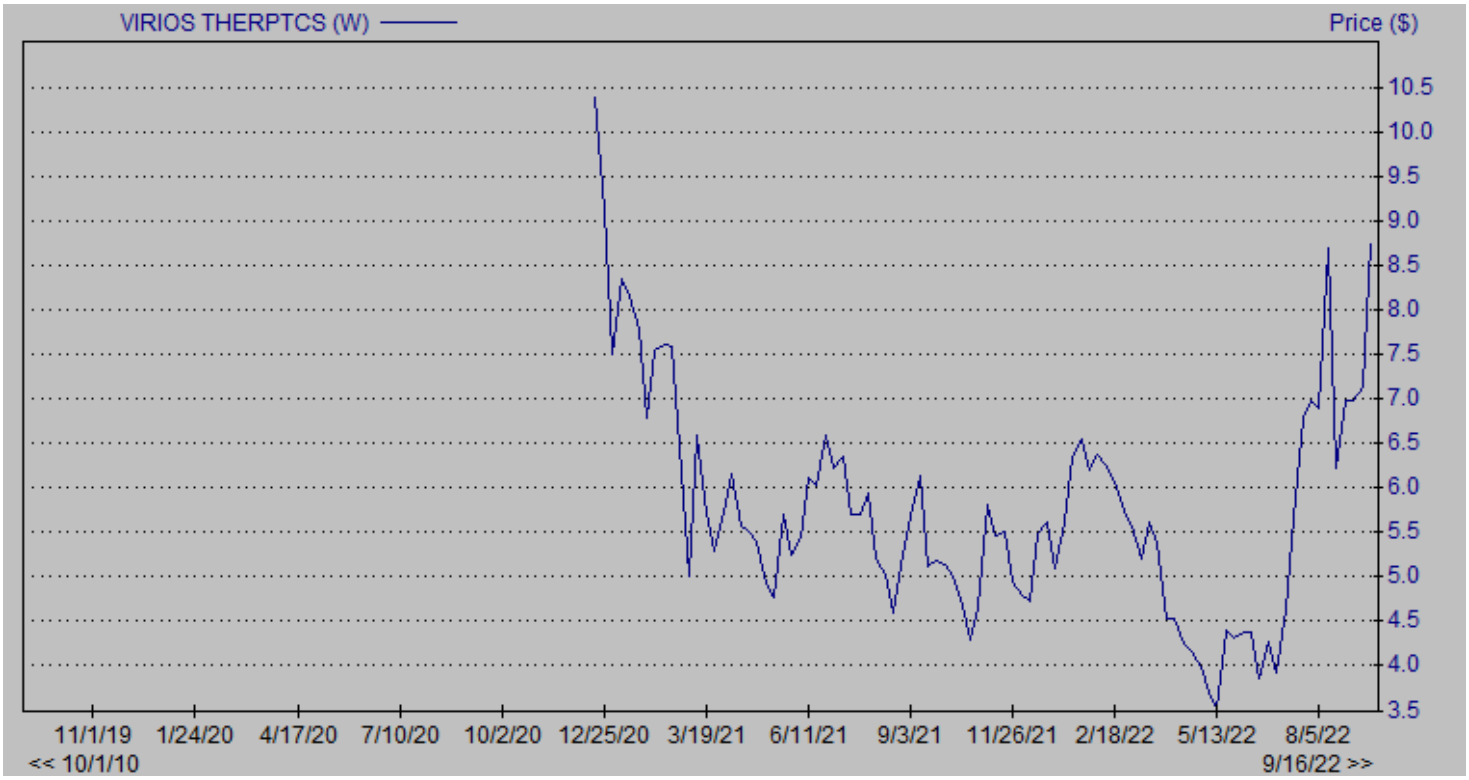
Based on the results of the FORTRESS trial we have lowered the probability of approval for IMC-1 in FM to 20%, raised the discount rate to 15%, and increased the future dilution to account for additional financings. This has results in a decrease of our valuation to $7 per share.

PROJECTED FINANCIALS

Virios Therapeutics, Inc.	2021 A	Q1 A	Q2 A	Q3 E	Q4 E	2022 E	2023 E	2024 E
IMC-1	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Other Income	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Total Revenues	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**
CoGS	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Product Gross Margin	-	-	-	-	-	-	-	-
R&D	$10.8	$2.8	$2.4	$3.0	$3.0	$11.2	$14.0	$16.0
SG&A	$4.8	$1.2	$1.3	$1.3	$1.3	$5.1	$5.5	$5.7
Operating Income	($15.6)	($4.0)	($3.7)	($4.3)	($4.3)	($16.2)	($19.5)	($21.7)
Operating Margin	-	-	-	-	-	-	-	-
Interest & Other Income	($0.3)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.1	$0.1
Pre-Tax Income	($16.0)	($4.0)	($3.7)	($4.3)	($4.3)	($16.2)	($19.4)	($21.6)
Taxes & Other	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($16.0)	($4.0)	($3.7)	($4.3)	($4.3)	($16.2)	($19.4)	($21.6)
Reported EPS	**($1.92)**	**($0.48)**	**($0.44)**	**($0.52)**	**($0.51)**	**($1.94)**	**($1.94)**	**($2.16)**
Weighted Shares Outstanding	8.3	8.3	8.3	8.3	8.3	8.3	10.0	10.0

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

HISTORICAL STOCK PRICE



Source: Zacks Small Cap Research

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