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Virios Therapeutics, Inc. (VIRI-NASDAQ)

VIRI: Ready to Approach FDA with Phase 3 Plans…

Based on our probability adjusted DCF model that takes into account potential future revenues of IMC-1, VIRI is valued at $2.00/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 (11/22/22)	$0.31
Valuation	**$2.00**

OUTLOOK

On November 14, 2022 Virios Therapeutics, Inc. (VIRI) announced financial results for the third quarter of 2022 and provided a business update. Since announcing topline results for the Phase 2b FORTRESS trial of IMC-1 in fibromyalgia (FM), the company has been trying to understand why that study was unsuccessful. A post-hoc analysis revealed that patients who were generally more naïve to prior clinical trials and prior fibromyalgia drug treatment showed clinically and statistically significant reductions in pain, fatigue, FM symptoms, and both anxiety and depression symptoms when treated with IMC-1. This is in contrast to FM patients who were in previous clinical trials and/or study site database patients, who did not exhibit a statistically significant treatment effect. The company will be requesting an 'end of Phase 2' meeting with the FDA to propose moving to a Phase 3 program focused on FM patients that are new to clinical trials. We anticipate Virios meeting with the FDA in the first half of 2023 such that the Phase 3 program can begin later in the year.

SUMMARY DATA

52-Week High	**$8.77**
52-Week Low	**$0.28**
One-Year Return (%)	**-93.85**
Beta	**1.61**
Average Daily Volume (sh)	**250,478**
Shares Outstanding (mil)	**8**
Market Capitalization ($mil)	**$3**
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	**Small-Value**
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 A	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	-$0.28 A	-$0.16 E	-$1.19 E
2023					-$0.97 E
2024					-$0.72 E

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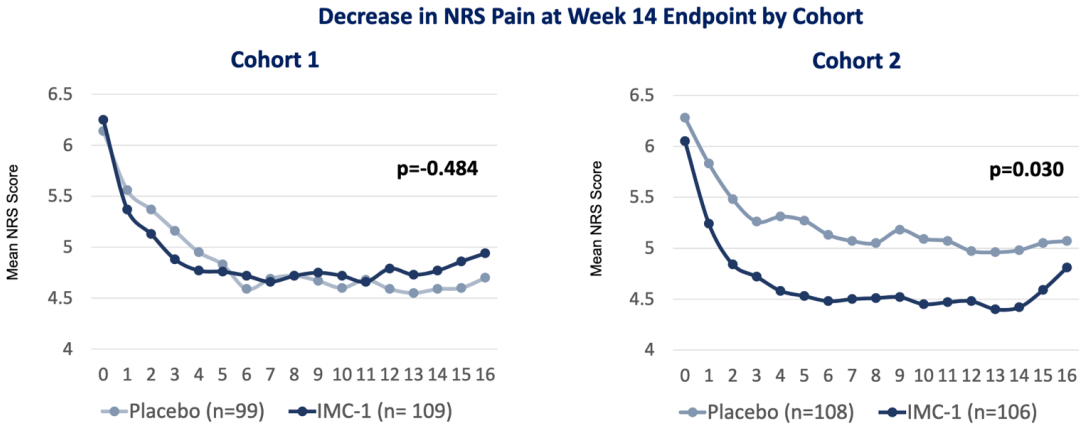
Business Update

Post-Hoc Analysis of Phase 2b FORTRESS Trial Shows Naïve Patients Responded to IMC-1 Treatment

In September, 2022, Virios Therapeutics, Inc. (VIRI) announced topline results for 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). Please see our previous report for a full discussion of the topline results.

Since that time, the company has undertaken a full analysis of the trial results to better understand what may have influenced the final outcome. The initial analysis of the data showed that for patients recruited in the first half of the study (Cohort 1: May 2021 – October 2021), there was a very high placebo response rate. This is in contrast to patients recruited in the second half of the trial (Cohort 2: November 2021 – April 2022), in which the placebo response rate was consistent with prior FM trials. In a post-hoc analysis, the patients recruited from November 2021 – April 2022 demonstrated a statistically and clinically significant improvement in the primary outcome of reduction in pain, which the company believes is unlikely related to chance. This is shown in the following image.



Source: Virios Therapeutics, Inc.

A deeper look at the data showed that "new" patients (recruited into the FORTRESS study via advertising) showed a statistically significant reduction in the primary endpoint, fatigue, anxiety and depressive symptoms, and an overall improvement in their global health status, regardless of when they were enrolled into the study. This is in contrast to "experienced" FM patients who had experience in previous clinical trials and treatment for FM, who did not exhibit any meaningful treatment benefits. The following table shows the primary endpoint of reduction in pain for "new" vs. "experienced" patients.

New vs Existing Patients	N	Placebo Change from Baseline @ Week 14	IMC-1 Change from Baseline @ Week 14	Contrast @ Week 14	P Value
Existing	247	-1.843	-1.594	+0.249	***
Advertising/ New	175	-1.024	-1.689	-0.665	0.016

Source: Virios Therapeutics, Inc.

Interestingly, approximately 70% of patients recruited during the first half of the FORTRESS trial (May 2021 – October 2021) were “experienced” patients. This may help to explain why there was no statistically significant treatment effect for the patients recruited during the first half of the trial, as the “experienced” patients may represent a more treatment refractory population.

With this information in hand, the company has decided that the Phase 3 program will focus on the “new” patient population, with those individuals typically recruited to the trial through advertising. In addition, the company found that dedicated clinical research sites delivered more consistent results, including better placebo response management, as opposed to clinical practice sites, thus the Phase 3 program will focus on dedicated research sites.

Importantly, the safety and tolerability of IMC-1 was better in the FORTRESS trial than in the previous Phase 2a trial, with fewer than 5% of IMC-1-treated patients withdrawing from the study due to adverse events compared to 8.1% withdrawing due to adverse events in the placebo group.

Virios will be requesting an “End-of-Phase 2” meeting with the FDA to discuss its proposed Phase 3 program. We anticipate that meeting taking place in the first half of 2023. Following receipt of the meeting minutes, we anticipate a full update from the company regarding its plans for the Phase 3 program, however at this point we believe it will consist of two, large Phase 3 studies, at least one of which will include a celecoxib-only treatment group in addition to the IMC-1 and placebo treatment groups.

Financial Update

On November 14, 2022, Virios announced financial results for the third quarter of 2022. As expected, the company did not report any revenues for the third quarter of 2022. R&D expenses for the three months ending September 30, 2022 were $1.6 million compared to $3.0 million for the third quarter of 2021. The decrease was primarily due to decreased expenses for the FORTESS study, decreased spending on the toxicology program, and a decrease in manufacturing costs. G&A expenses for the third quarter of 2022 were $0.9 million compared to $1.1 million for the third quarter of 2021. The decrease was primarily due to a decrease in expenses in salaries and related costs.

As of September 30, 2022, Virios had approximately $9.8 million in cash and cash equivalents. We estimate the company has sufficient capital to fund operations through the end of 2023. As of November 11, 2022, Virios had approximately 18.3 million common shares outstanding and, when factoring in stock options and warrants, a fully diluted share count of approximately 20.3 million.

Conclusion

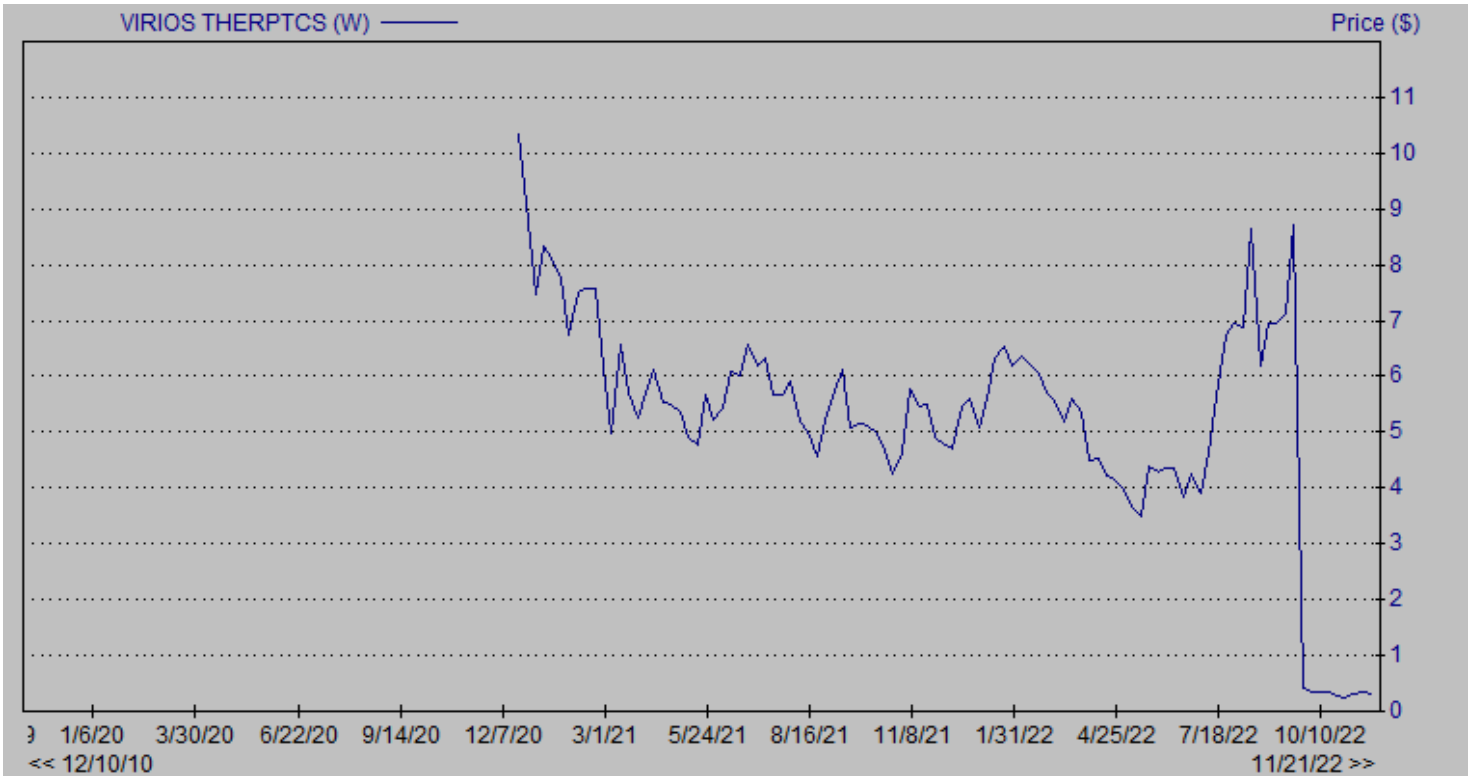
We are encouraged by the company’s post-hoc analysis of the FORTRESS data and the possible explanation for why the study was not positive. We look forward to the result of the meeting with the FDA, which we expect to occur in the first half of 2023. With no changes to our model our valuation remains at $2 per share.

PROJECTED FINANCIALS

Virios Therapeutics, Inc.	2021 A	Q1 A	Q2 A	Q3 A	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	$1.6	$2.0	$8.8	$14.0	$16.0
SG&A	$4.8	$1.2	$1.3	$1.0	$1.0	$4.4	$5.5	$5.7
Operating Income	($15.6)	($4.0)	($3.7)	($2.6)	($3.0)	($13.2)	($19.5)	($21.7)
Operating Margin	-	-	-	-	-	-	-	-
Interest & Other Income	($0.3)	$0.0	$0.0	$0.0	$0.0	$0.1	$0.1	$0.1
Pre-Tax Income	($16.0)	($4.0)	($3.7)	($2.6)	($3.0)	($13.2)	($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)	($2.6)	($3.0)	($13.2)	($19.4)	($21.6)
Reported EPS	**($1.92)**	**($0.48)**	**($0.44)**	**($0.28)**	**($0.16)**	**($1.19)**	**($0.97)**	**($0.72)**
Weighted Shares Outstanding	8.3	8.3	8.3	9.2	18.3	11.0	20.0	30.0

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

HISTORICAL STOCK PRICE



Source: Zacks Small Cap Research

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