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

VIRI: Phase 3 Program in Fibromyalgia to Initiate in mid-2024…

Based on our probability adjusted DCF model that takes into account potential future revenues of IMC-1, VIRI is valued at $3.50/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 (08/15/23)	$1.02
Valuation	**$3.50**

OUTLOOK

On August 10, 2023 Virios Therapeutics, Inc. (VIRI) announced financial results for the second quarter of 2023 and provided a business update. The company announced that the FDA performed an initial review of Virios' chronic toxicology program to support the safety of IMC-1 and determined that the studies appear adequate to support the use of IMC-1 at the proposed dose for treating fibromyalgia. Virios will soon be initiating a pharmacokinetic (PK) and food effect study for IMC-1 while simultaneously submitting a final Phase 3 program outline to the FDA. We anticipate the Phase 3 program for IMC-1 in fibromyalgia initiating in mid-2024. As a follow-up to the recently completed study of IMC-2 in Long COVID, a second investigator-initiated, double blind, placebo controlled study with the Bateman Horne Center will initiate in the Fall of 2023. The company is also planning to meet with the FDA to discuss the advancement of IMC-2 into Phase 2 development for the treatment of Long COVID.

SUMMARY DATA

52-Week High	**$8.77**
52-Week Low	**$0.24**
One-Year Return (%)	**-87.83**
Beta	**1.82**
Average Daily Volume (sh)	**801,518**
Shares Outstanding (mil)	**19**
Market Capitalization ($mil)	**$20**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**25**
Insider Ownership (%)	**10**
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-Growth**
Industry	**Med-Biomed/Gene**

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	-$0.48 A	-$0.44 A	-$0.28 A	-$0.11 A	-$1.11 A
2023	-$0.08 A	-$0.08 A	-$0.10 E	-$0.08 E	-$0.34 E
2024					-$0.37 E
2025					-$0.32 E

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WHAT'S NEW

Business Update

Update on Phase 3 Program for IMC-1 in Fibromyalgia

Virios Therapeutics, Inc. (VIRI) is developing IMC-1 (combination of famciclovir and celecoxib) as a therapy for fibromyalgia (FM). The company previously reported results from the Phase 2b FORTRESS trial in September 2022. Topline results showed that the 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 company performed a full analysis of the trial data, which showed that "new" patients (recruited into the FORTRESS study via advertising) exhibited 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.

With that 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 has proposed that the Phase 3 program include four primary components: two adequate and well controlled clinical trials, one of which will be a full factorial design with each of the individual components of IMC-1 (famciclovir and celecoxib) as separate comparator arm, a long-term safety trial, and a pharmacokinetic (PK) and food effect study. The PK and food effect study will initiate before the end of 2023.

Initial feedback by the FDA indicated that the proposed Phase 3 program is acceptable. In addition, the company announced that the FDA communicated that after their initial review of the chronic toxicology program, the programs studies appeared adequate to support the safety of IMC-1 at the proposed dose for use in treating fibromyalgia. We anticipate the first Phase 3 fibromyalgia study getting underway in mid-2024.

Second Long COVID Study to Initiate

Following the encouraging results from the open label, proof-of-concept trial of IMC-2 (combination of valacyclovir and celecoxib) for the treatment of Post-Acute Sequelae of COVID-19 infection (PASC), otherwise known as Long COVID, Virios will be sponsoring a second investigator-initiated study with the Bateman Horne Center this fall. The follow-up study will be a double blind, placebo controlled trial that will otherwise be very similar to the initial proof-of-concept study. In addition, Virios is planning to meet with the FDA in the second half of 2023 to discuss a proposal to advance IMC-2 into Phase 2 development for the treatment of Long COVID.

Financial Update

On August 10, 2023, Virios announced financial results for the second quarter of 2023. As expected, the company did not report any revenues for the second quarter of 2023. R&D expenses for the three months ending June 30, 2023 were $0.6 million compared to $2.4 million for the second quarter of 2022. The decrease was primarily due to decreased clinical trial and animal toxicology expenses. G&A expenses for the second quarter of 2023 were $0.9 million compared to $1.3 million for the second quarter of 2022. The decrease was primarily due to a decrease in expenses associated with being a public company, legal and accounting feels, and salaries and related costs.

As of June 30, 2023, Virios had approximately $4.6 million in cash and cash equivalents. We estimate the company has sufficient capital to fund operations for at least the next 12 months. As of August 9, 2023, Virios had approximately 19.2 million common shares outstanding and, when factoring in stock options and warrants, a fully diluted share count of approximately 21.8 million.

Conclusion

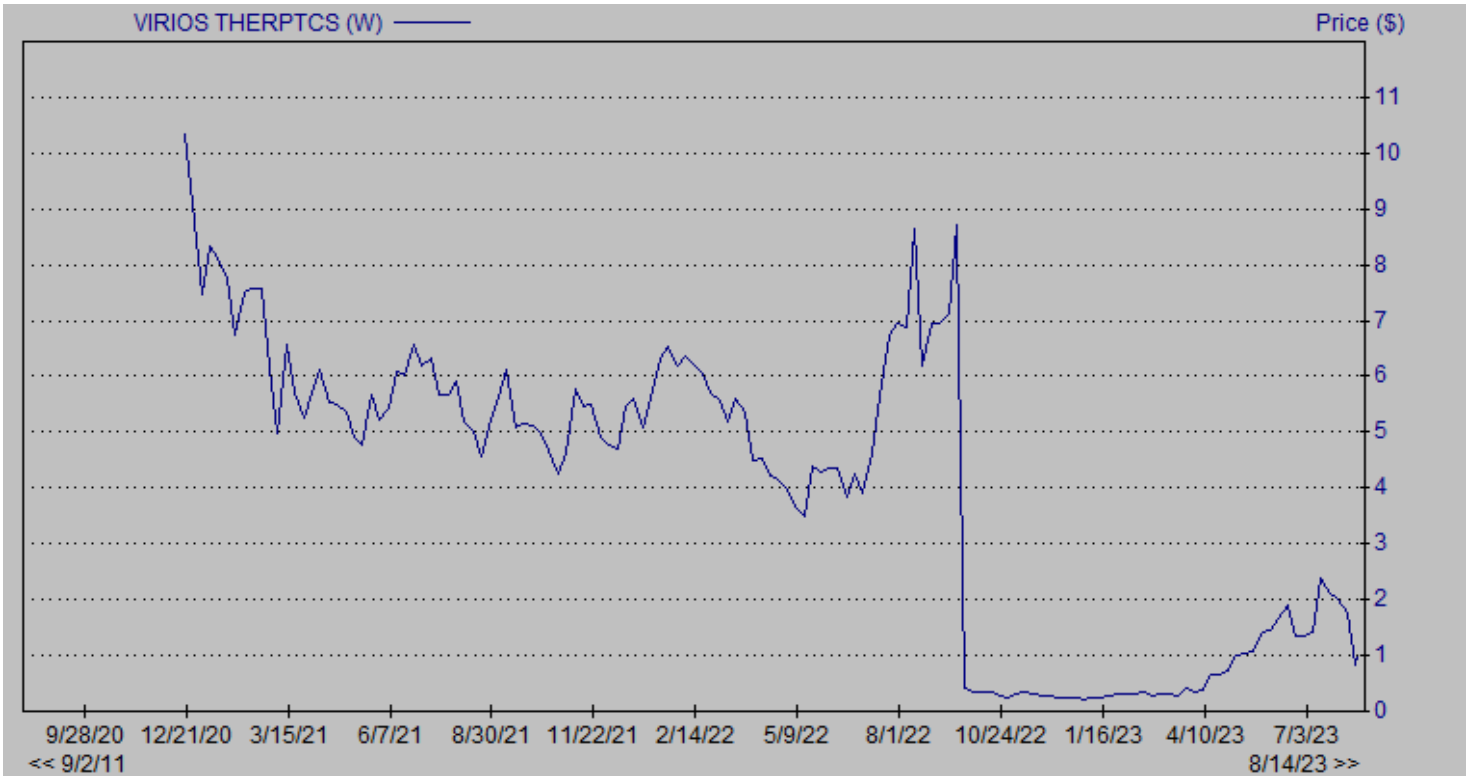
We're glad to see that the FDA has stated that the chronic toxicology results for IMC-1 support its safe use at the proposed dose for the treatment of fibromyalgia. We look forward to additional details regarding the design of the Phase 3 program for IMC in fibromyalgia following the company's meeting with the FDA. We also expect the company to announce additional details of the Phase 2 program for IMC-2 in Long COVID following a meeting with the FDA. With no changes to our model our valuation remains at $3.50 per share.

PROJECTED FINANCIALS

Virios Therapeutics, Inc.	2022 A	Q1 A	Q2 A	Q3 E	Q4 E	2023 E	2024 E	2025 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	$8.1	$0.5	$0.6	$0.8	$1.0	$2.9	$10.0	$11.0
SG&A	$4.2	$1.1	$0.9	$1.2	$1.2	$4.4	$4.8	$5.0
Operating Income	($12.3)	($1.6)	($1.5)	($2.0)	($2.2)	($7.2)	($14.8)	($16.0)
Operating Margin	-	-	-	-	-	-	-	-
Interest & Other Income	$0.1	$0.0	$0.0	$0.0	$0.0	$0.1	$0.1	$0.1
Pre-Tax Income	($12.2)	($1.5)	($1.4)	($2.0)	($2.2)	($7.1)	($14.7)	($15.9)
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	($12.2)	($1.5)	($1.4)	($2.0)	($2.2)	($7.1)	($14.7)	($15.9)
Reported EPS	**($1.11)**	**($0.08)**	**($0.08)**	**($0.10)**	**($0.08)**	**($0.34)**	**($0.37)**	**($0.32)**
Weighted Shares Outstanding	11.1	18.3	18.4	19.2	28.0	21.0	40.0	50.0

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

HISTORICAL STOCK PRICE



Source: Zacks Small Cap Research

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