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November 13, 2023
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Virios Therapeutics, Inc.

(VIRI-NASDAQ)

VIRI: Provides Overview of Phase 3 Program in Fibromyalgia…

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 (11/13/23)	$0.77
Valuation	**$3.50**

OUTLOOK

On November 13, 2023 Virios Therapeutics, Inc. (VIRI) announced financial results for the third quarter of 2023 and provided a business update. The company provided an overview of the planned Phase 3 program for IMC-1 in fibromyalgia (FM), which will include two efficacy studies (IMC-1 vs. placebo; IMC-1 vs. placebo vs. famciclovir vs. celecoxib), a pharmacokinetic/food effect study, and a long-term extension trial. The company is planning to initiate the program in mid-2024 and it is currently engaged with a number of life sciences companies regarding potential partnership opportunities. A second investigator-sponsored trial of IMC-2 as a treatment for Long COVID is planned to be performed at the Bateman Horne Center that will examine two different doses of IMC-2 versus placebo. The results of that study will guide the design of a Phase 2 study to be conducted by Virios.

SUMMARY DATA

52-Week High	**$2.42**
52-Week Low	**$0.24**
One-Year Return (%)	**115.28**
Beta	**2.15**
Average Daily Volume (sh)	**943,672**
Shares Outstanding (mil)	**19**
Market Capitalization ($mil)	**$15**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**11**
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-Blend**
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 A	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	-$0.06 A	-$0.11 E	-$0.34 E
2024					-$0.37 E
2025					-$0.32 E

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WHAT'S NEW

Business Update

Overview of 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.

The company recently provided an overview of the planned Phase 3 program in FM as it has now secured agreement with the FDA on the plan. It will consist of four components: 1) a pharmacokinetic/food effect study; 2) Study 301: a head-to-head comparison of IMC-1 vs. placebo with a 1:1 randomization of 160 patients per group. The primary endpoint will be reduction in pain at 12 Weeks; 3) Study 302: a multifactorial study of IMC-1 vs. placebo vs. famciclovir reference drug tablet vs. celecoxib reference drug capsule. Each group will have 160 patients and the primary endpoint will be reduction in pain at 12 Weeks; 4) Study 309: this will be a long-term extension study where patients from both Study 301 and Study 302 will be offered the opportunity to enroll. The company is targeting treatment with IMC-1 for a year, with approximately 300 patients being treated for at least six months and approximately 100 patients being treated for at least one year. In addition, based on the results discussed above, the Phase 3 program will focus on "new" FM patients, which refers to patients who have not been in previous FM clinical trials.

Virios has indicated that it is in active discussions with several life sciences companies that are reviewing the Phase 2 data and the proposed Phase 3 program for a potential development partnership. However, a partnership is not a pre-requisite for initiating the Phase 3 program as the company is prepared to move forward on its own.

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. The follow-up study will be a double blind, placebo controlled trial that will test two doses of IMC-2 vs. placebo. The study will enroll 20 patients per cohort for a total of 60 patients. In addition, Virios has submitted briefing materials to the FDA concerning submission of a proposed investigational drug application (IND) for IMC-2 as a treatment for Long COVID and is awaiting a response from the agency.

Financial Update

On November 13, 2023, Virios announced financial results for the third quarter of 2023. As expected, the company did not report any revenues for the third quarter of 2023. R&D expenses for the three months ending September 30, 2023 were $0.4 million compared to $1.6 million for the third quarter of 2022. The decrease was primarily due to decreased clinical trial and manufacturing expenses. G&A expenses for the third quarter of 2023 were $0.9 million compared to $1.0 million for the third quarter of 2022. The decrease was primarily due to a decrease in expenses associated with being a public company.

As of September 30, 2023, Virios had approximately $4.8 million in cash and cash equivalents. We estimate the company has sufficient capital to fund operations into the third quarter of 2024. As of November 9, 2023, Virios had approximately 19.3 million common shares outstanding and, when factoring in stock options and warrants, a fully diluted share count of approximately 21.4 million.

Conclusion

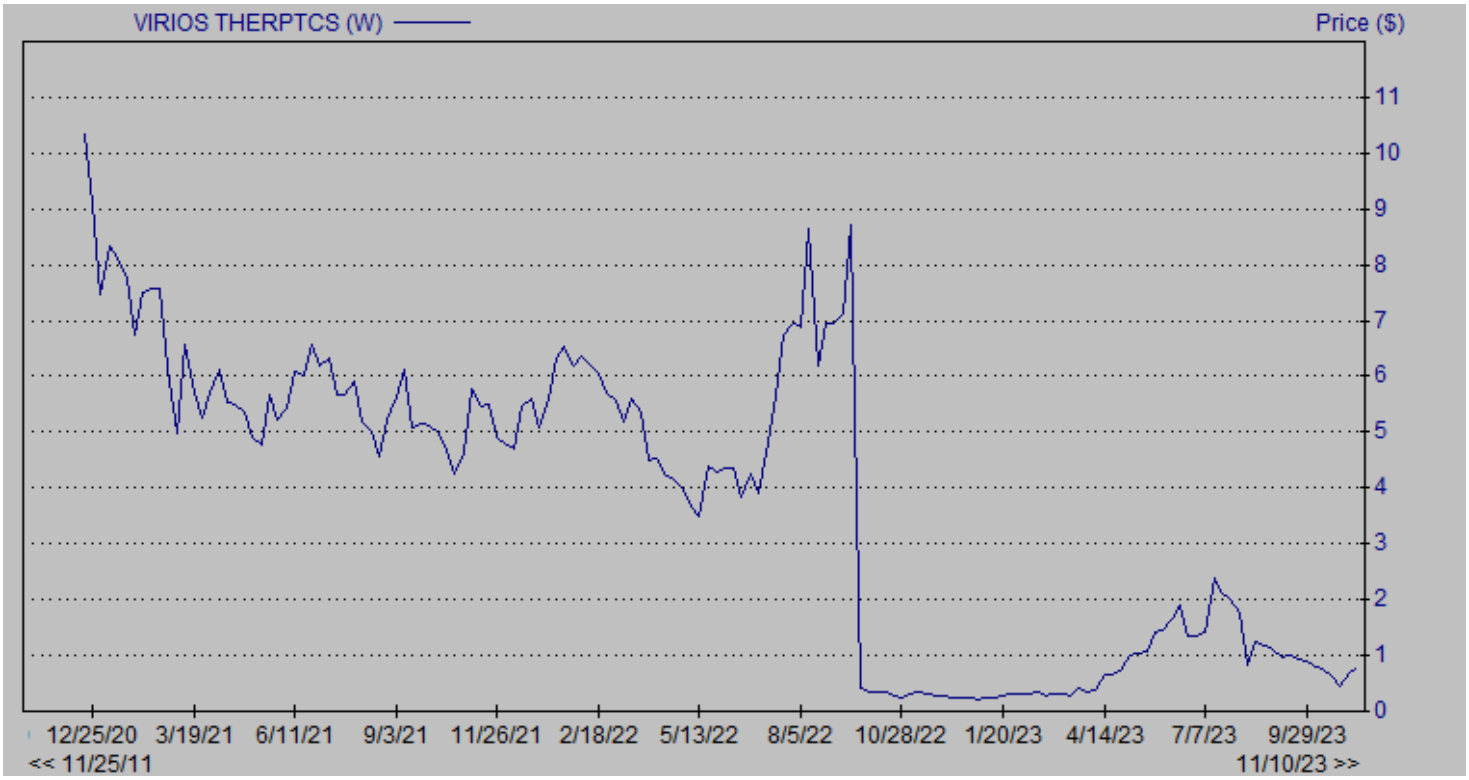
Virios now has a plan in place for the Phase 3 program in FM and it's good to hear that there are active discussions going on with potential partnering companies. We look forward to results from the second Long COVID trial taking place at the Bateman Horne Center as well as the feedback the company receives from the FDA regarding the IND for Long COVID. 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 A	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	$0.4	$1.0	$2.4	$10.0	$11.0
SG&A	$4.2	$1.1	$0.9	$0.9	$1.2	$4.1	$4.8	$5.0
Operating Income	($12.3)	($1.6)	($1.5)	($1.3)	($2.2)	($6.5)	($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)	($1.2)	($2.2)	($6.4)	($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)	($1.2)	($2.2)	($6.4)	($14.7)	($15.9)
Reported EPS	**($1.11)**	**($0.08)**	**($0.08)**	**($0.06)**	**($0.11)**	**($0.34)**	**($0.37)**	**($0.32)**
Weighted Shares Outstanding	11.1	18.3	18.4	19.1	19.3	18.8	40.0	50.0

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

HISTORICAL STOCK PRICE



Source: Zacks Small Cap Research

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