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David Bautz, PhD
(312) 265-9471
dbautz@zacks.com

scr.zacks.com
10 S. Riverside Plaza, Chicago, IL 60606

Virios Therapeutics, Inc. (VIRI-NASDAQ)

VIRI: Topline Results for FORTRESS Trial Expected in September 2022…

Based on our probability adjusted DCF model that takes into account potential future revenues of IMC-1, VIRI is valued at $22.00/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 (08/15/22)	$8.70
Valuation	**$22.00**

OUTLOOK

On August 11, 2022, Virios Therapeutics, Inc. (VIRI) announced financial results for the second quarter of 2022 and provided a business update. Virios recently completed patient dosing in the Phase 2b FORTRESS trial of IMC-1, the company's novel, proprietary, fixed dose combination of famciclovir and celecoxib that is designed to synergistically suppress herpes virus activation and replication. We anticipate topline results being announced in September 2022. In addition to the FORTRESS trial, Virios has entered into a research collaboration with the Bateman House Center (BHC) to study the effect of combination antiviral therapy for the treatment of Long COVID. While Virios does not control the timing of that study, the BHC has indicated that recruitment should be complete by the end of 2022 and topline results should be available in the first half of 2023.

SUMMARY DATA

52-Week High	**$8.70**
52-Week Low	**$3.31**
One-Year Return (%)	**72.28**
Beta	**0.64**
Average Daily Volume (sh)	**30,225**
Shares Outstanding (mil)	**8**
Market Capitalization ($mil)	**$72**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**11**
Insider Ownership (%)	**19**
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	**Above Avg.**
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

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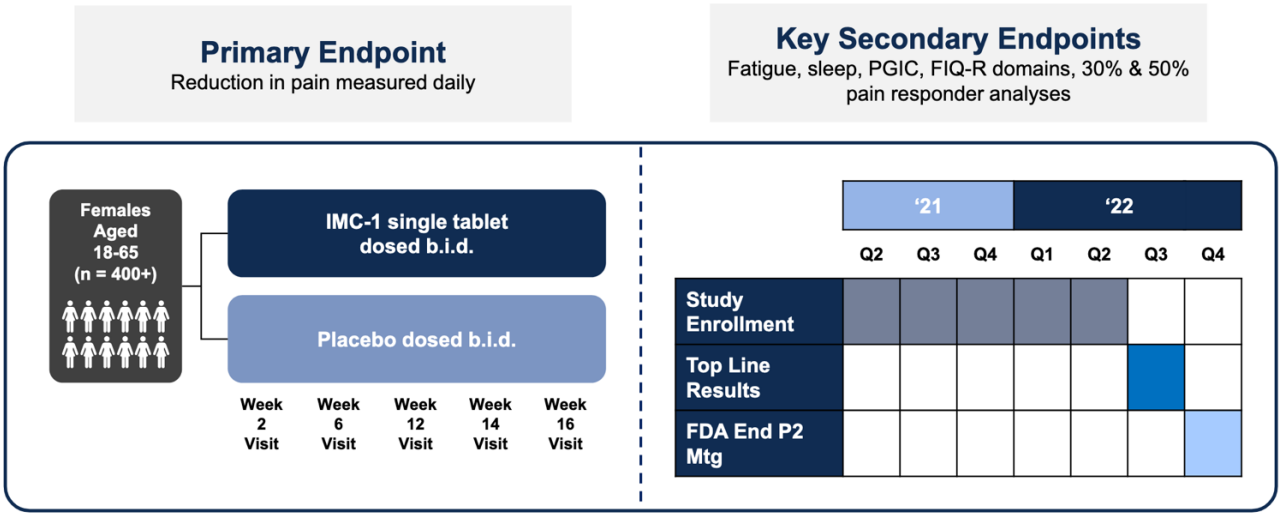
Business Update

FORTRESS Trial Dosing Complete; Topline Results in September 2022

Virios Therapeutics, Inc. (VIRI) recently announced that it has completed dosing for all 425 fibromyalgia patients in the Phase 2b FORTRESS (Fibromyalgia Outcome Research Trial Evaluating Synergistic Suppression of Herpes Simplex Virus-1) trial, a randomized, double blind, placebo controlled study of IMC-1. The primary endpoint of the trial is reduction in pain and secondary endpoints include change in fatigue, sleep disturbance, global health status, and patient functionality (NCT04748705). An outline of the trial is shown below.



Source: Virios Therapeutics, Inc.

In parallel with the FORTRESS trial, Virios recently completed the chronic toxicology studies of IMC-1 in two animal species. The results of these studies are required by regulators before Virios will be allowed to dose patients for one year or more, which is the plan for the Phase 3 program. The results will be included in the package that the company will submit to the FDA to facilitate discussions regarding the Phase 3 program.

Testing Combination Antiviral Therapy for the Treatment of Long COVID

In February 2022, Virios announced a collaboration with the Bateman Horne Center (BHC) to test combination antiviral therapy for the treatment of Long COVID. Following an infection with SARS-CoV-2, the virus that causes COVID-19, approximately 30% of patients will experience symptoms that last for weeks or months, which is referred to as Long COVID. The range of symptoms varies from patient to patient, however the most commonly reported (from a recent meta analysis) were fatigue (58%), headache (44%), attention disorder (27%), hair loss (25%), and dyspnea (24%) (Lopez-Leon *et al.*, 2021).

The main theories for what might be causing Long COVID include:

- The SARS-CoV-2 virus remains hidden in the body and continues to inflict damage
- An overreactive immune system set off by the SARS-CoV-2 virus remains at an elevated state, which may include the development of autoantibodies
- Immune suppression caused by the SARS-CoV-2 infection leads to the reactivation of a dormant virus

The trial will test the hypothesis that a dormant virus is being reactivated in Long COVID patients. This is a natural fit with what Virios is currently testing in patients with fibromyalgia (FM), in which the reactivation of the herpes simplex virus-1 (HSV-1) is hypothesized to be driving the disease. While Virios is testing IMC-1 (a

combination therapy of famciclovir and celecoxib) in patients with FM, BHC will be testing IMC-2 (a combination of valacyclovir and celecoxib) in patients with Long COVID since it is their hypothesis that a herpesvirus (e.g., Epstein-Barr virus; EBV) could be to blame. BHC has chosen to test valacyclovir as part of the combination therapy since previous results suggest that valacyclovir is effective in reducing the number of EBV-infected B cells (Hoshino *et al*., 2009).

On August 15, 2022, Virios announced that the first patient was dosed in the Long COVID trial and we anticipate the trial enrolling approximately 25-30 Long COVID patients with a control group to be comprised of a cohort of Long COVID patients treated by BHC with similar demographics. The study subjects will be treated for 14 weeks with a number of parameters being examined such as fatigue and brain fog. We anticipate topline data in the first half of 2023.

BHC is a non-profit, interdisciplinary Center of Excellence with a focus on treating myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS), FM, post-viral syndromes, and related comorbidities, thus making them an excellent collaborator for Virios. While exploratory, this study expands Virios' pipeline and, with an estimated 373 million SARS-CoV-2 infections already being reported, represents an enormous potential opportunity should IMC-2 be effective.

Financial Update

On August 11, 2022, Virios announced financial results for the second quarter of 2022. As expected, the company did not report any revenues for the second quarter of 2022. R&D expenses for the three months ending June 30, 2022 were $2.4 million compared to $3.2 million for the second quarter of 2021. The decrease was primarily due to decreased expenses for related to the toxicology studies. G&A expenses for the second quarter of 2022 were $1.3 million compared to $1.1 million for the second quarter of 2021. The increase was primarily due to a increases in legal and accounting fees and increased salaries.

As of June 30, 2022, Virios had approximately $7.7 million in cash and cash equivalents. We estimate the company has sufficient capital to fund operations through the end of 2022. As of August 11, 2022, Virios had approximately 8.3 million common shares outstanding and, when factoring in stock options and warrants, a fully diluted share count of approximately 9.8 million.

Conclusion

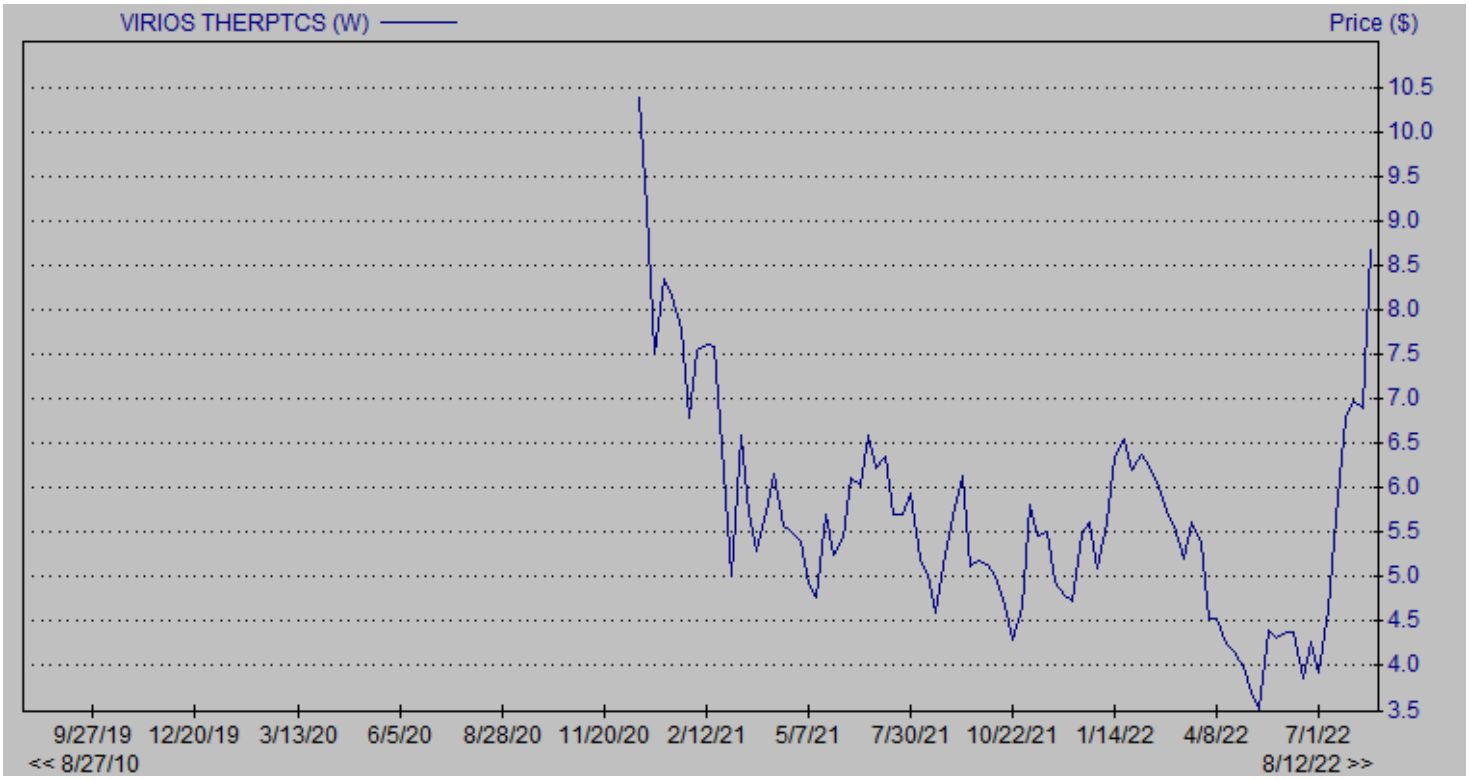
With dosing complete in the Phase 2b FORTRESS study, the countdown begins to the release of topline results, which we believe will occur in September 2022. With the chronic toxicology studies complete, Virios should be in position to approach the FDA about advancing IMC-1 into a Phase 3 program in fibromyalgia pending positive results from the FORTRESS study. We are also glad to see the Long COVID study get underway and we look forward to results from the trial in the first half of 2023. With no changes to our model, our valuation remains at $22.

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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