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Virios Therapeutics, Inc.

(VIRI-NASDAQ)

VIRI: Enrollment Ongoing for IMC-1 Phase 2b Trial…

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 (08/16/21)	$5.05
Valuation	**$22.00**

OUTLOOK

On August 12, 2021, Virios Therapeutics, Inc. (VIRI) announced financial results for the second quarter of 2021 and provided a business update. The company is currently conducting the Phase 2b FORTRESS trial of its lead compound, IMC-1. Over 40 clinical sites are activated and patient enrollment is progressing nicely. We anticipate topline results from the trial in mid-2022. The company is also in the process of identifying other potential indications for which IMC-1 may be utilized, which could include irritable bowel disease (IBS), chronic fatigue syndrome (CFS), or Long COVID. We anticipate an update from the company in the second half of 2021 on potential pipeline expansion.

SUMMARY DATA

52-Week High	**$16.71**
52-Week Low	**$4.71**
One-Year Return (%)	**N/A**
Beta	**N/A**
Average Daily Volume (sh)	**41,756**
Shares Outstanding (mil)	**8**
Market Capitalization ($mil)	**$42**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**10**
Insider Ownership (%)	**N/A**
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)
2020	0 A	0 A	0 A	0 A	0 A
2021	0 A	0 A	0 E	0 E	0 E
2022					0 E
2023					0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2020				-$1.25 A	-$2.10 A
2021	-$0.37 A	-$0.51 A	-$0.70 E	-$0.83 E	-$2.41 E
2022					-$3.05 E
2023					-$2.73 E

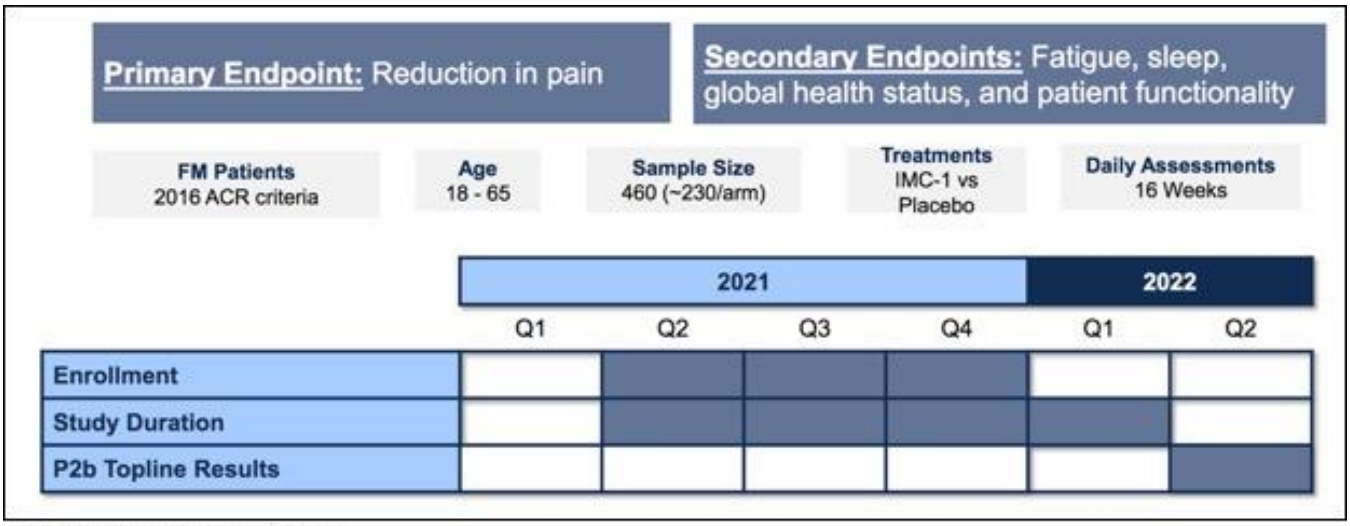
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WHAT'S NEW

Business Update

Enrollment Continuing in Phase 2b FORTRESS Trial

Virios Therapeutics, Inc. (VIRI) is currently conducting the Phase 2b FORTRESS (Fibromyalgia Outcome Research Trial Evaluating Synergistic Suppression of HSV-1) trial of IMC-1 in patients with fibromyalgia (FM). It is a randomized, double blind, placebo controlled, multi-center trial with a primary endpoint of reduction in pain and secondary endpoints including change in fatigue, sleep disturbance, global health status, and patient functionality (NCT04748705). Approximately 460 females between the ages of 18-65 will be enrolled with a study duration of 16 weeks. An outline of the trial is shown below.



Source: Virios Therapeutics, Inc.

During the second quarter conference call update, management indicated that 41 centers are now operational and patient enrollment is progressing on track with approximately 100 patients having been randomized into the trial thus far. In addition, as of now there has been no effect on enrollment due to the increasing number of COVID-19 cases in the U.S. and based on prior experience Virios does not forecast there being major changes to the rate of enrollment due to COVID-19. We continue to estimate that topline results for the FORTRESS trial will be available in mid-2022.

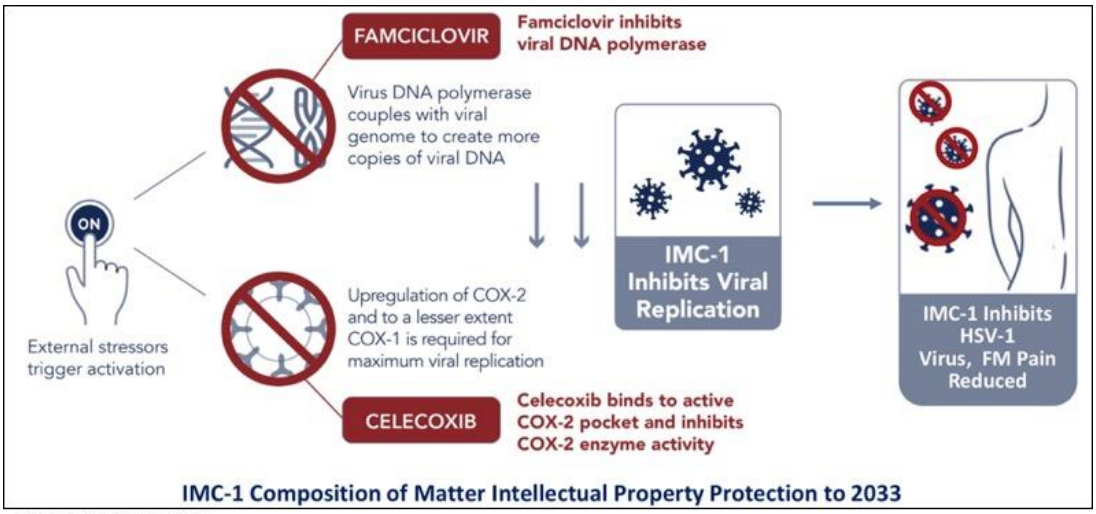
Background on IMC-1

Virios' technology is predicated on the hypothesis that the root cause of FM is an abnormal immune response to a reactivated herpes simplex virus-1 (HSV-1) infection. HSV-1 is a double-stranded DNA virus that causes cold sores in and around the mouth. Approximately 50-80% of adults in the U.S. are infected with the virus, however not everyone shows signs of infection. Once infected, an individual with HSV-1 will have the virus for the rest of their life, with the virus normally residing dormant in neuronal nuclei.

The impetus for using an antiviral plus a COX-2 inhibitor as a treatment for FM was based on the observation that patients with irritable bowel syndrome (IBS) treated with famciclovir, who also happened to be taking celecoxib concurrently to treat other conditions (e.g., osteoarthritis), showed significant improvement in their IBS, FM, fatigue, and headaches. This observation lead to the hypothesis that stress or other environmental factors reactivate a latent HSV-1 infection that results in a continuous nociceptive stimulation and heightened immune response. (Bond, 1993).

IMC-1, Virios' lead development product, consists of a proprietary mixture of the anti-viral drug famciclovir and the COX-2 inhibitor celecoxib. Famciclovir is a guanosine analogue that was first approved by the FDA in

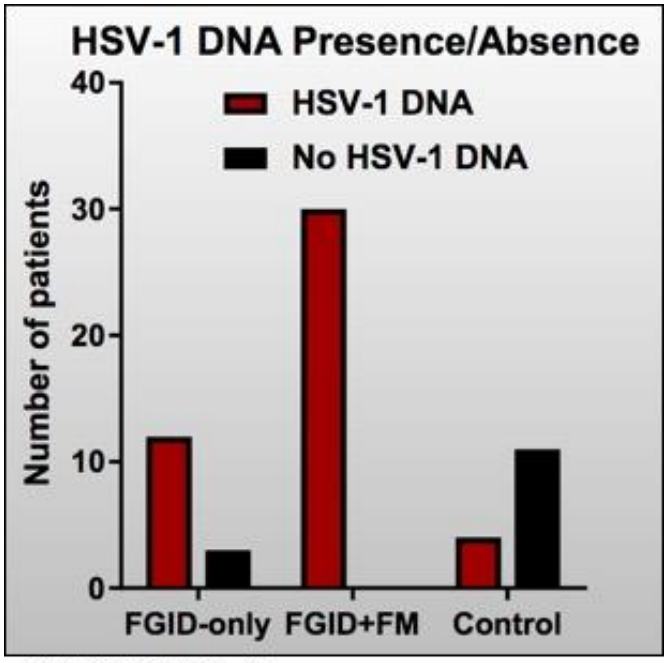
1994 and is used for the treatment of various herpesvirus infections (shingles, cold sores, genital herpes). It works through inhibition of DNA replication. Celecoxib is a nonsteroidal anti-inflammatory drug (NSAID) that is highly selective for the COX-2 isoform of cycolooxygenase and is used to treat pain and inflammation. Non-selective NSAIDs (aspirin, ibuprofen, naproxen) inhibit both COX-1 and COX-2 and are associated with gastrointestinal side effects, which a COX-2 selective inhibitor can minimize. In addition to its analgesic and anti-inflammatory properties, COX-2 inhibitors were shown to suppress HSV-1 activation (Gebhardt *et al*., 2005). Thus, by combining famciclovir and celecoxib, Virios is hoping to return HSV-1 to a dormant state through two separate mechanisms of action and decrease the associated aberrant immune response.



Source: Virios Therapeutics, Inc.

Additional Indications for IMC-1

During the second quarter conference call, management indicated that there is increasing recognition in the scientific community of the potential role for reactivated viruses (such as HSV-1) as the cause of a wide range of conditions including FM, irritable bowel syndrome (IBS), and fatigue related disorders (e.g., chronic fatigue syndrome). According to management, the two that the company is focused on beyond FM right now are IBS and fatigue related disorders. As shown in the following figure, a study at the University of Alabama showed that the majority of a population of patients with functional gastrointestinal disorders (FGID) tested positive for HSV-1 DNA, suggesting it may play a role in the disease.



Source: Virios Therapeutics, Inc.

Data from the company's Phase 2a clinical trial of IMC-1 in FM showed that the drug significantly reduced FM-related pain, which serves as an excellent proof-of-concept for the potential utility of using IMC-1 to treat IBS pain. In addition, there is a significant unmet medical need in the IBS marketplace with few effective treatment options for patients. We anticipate Virios providing a formal update on which indications the company will be pursuing in the second half of 2021.

Financial Update

On August 12, 2021, Virios announced financial results for the second quarter of 2021. As expected, the company did not report any revenues for the second quarter of 2021. R&D expenses for the three months ending June 30, 2021 increased by $3.2 million compared to the second quarter of 2020. The increase was primarily due to increased expenses for clinical trials, toxicology studies, salaries, and drug development and manufacturing. G&A expenses increased by $0.6 million for the second quarter of 2021 compared to the prior year period. The increase was primarily due to increased costs associated with being a public company.

As of June 30, 2021, Virios had approximately $21.8 million in cash and cash equivalents. We estimate the company has sufficient capital to fund operations through the end of 2022. As of August 12, 2021, Virios had approximately 8.3 million common shares outstanding and, when factoring in stock options and warrants, a fully diluted share count of approximately 9.5 million.

Conclusion

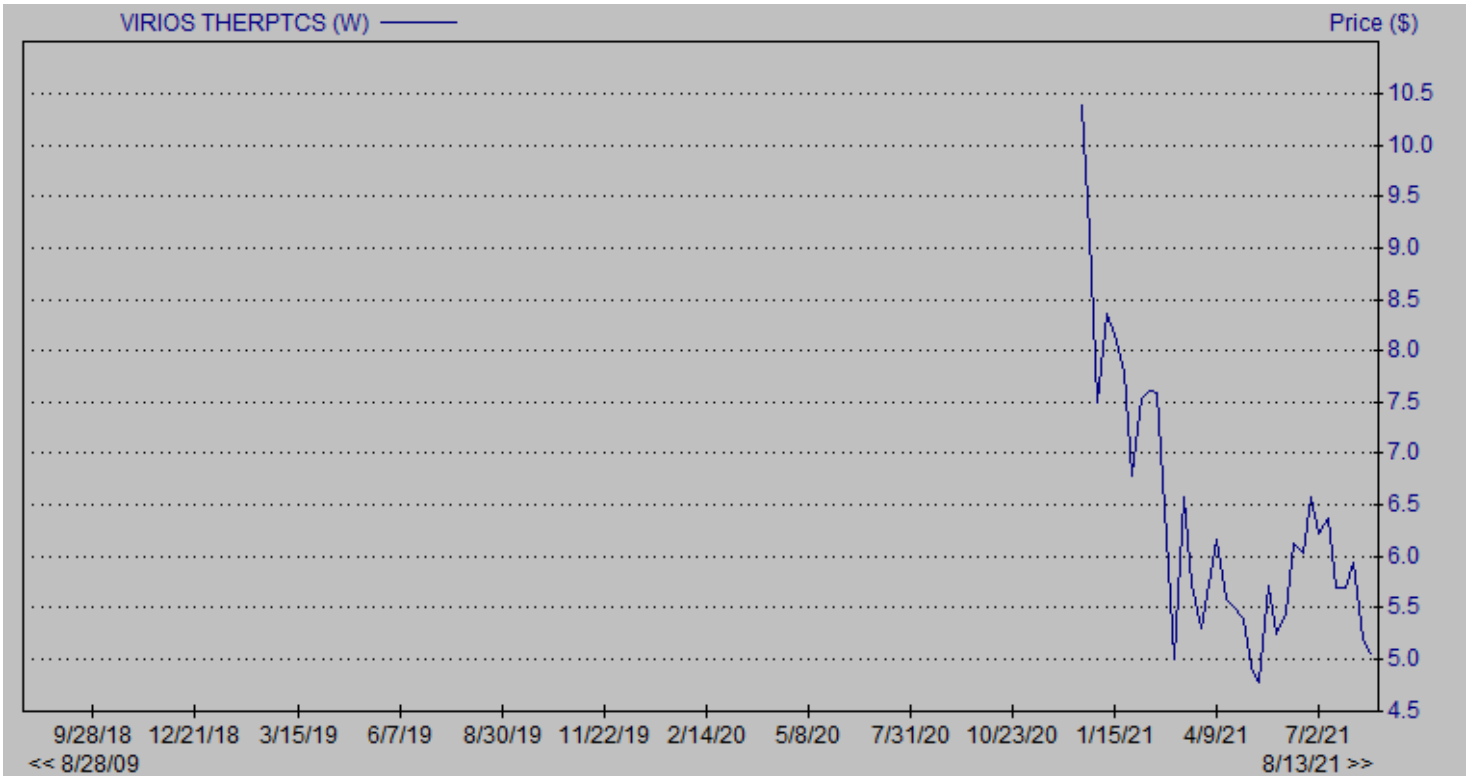
We're glad to see that all the clinical trial sites for the Phase 2b FORTRESS trial are operational and that patient enrollment is progressing as planned. We continue to estimate that topline results will be available in mid-2022. In addition, we look forward to an update from the company in the second half of 2021 on which other indication(s) IMC-1 will be developed. With no changes to our model our valuation remains at $22 per share.

PROJECTED FINANCIALS

Virios Therapeutics, Inc.	2020 A	Q1 A	Q2 A	Q3 E	Q4 E	2021 E	2022 E	2023 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	$0.2	$1.7	$3.2	$3.0	$4.0	$11.9	$15.0	$20.0
SG&A	$9.8	$1.4	$1.1	$2.9	$3.0	$8.3	$12.0	$13.0
Operating Income	($10.0)	($3.1)	($4.3)	($5.9)	($7.0)	($20.2)	($27.0)	($33.0)
Operating Margin	-	-	-	-	-	-	-	-
Interest & Other Income	($0.3)	$0.0	$0.0	$0.0	$0.0	$0.1	$0.2	$0.2
Pre-Tax Income	($10.3)	($3.1)	($4.3)	($5.9)	($7.0)	($20.2)	($26.8)	($32.8)
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	($10.3)	($3.1)	($4.3)	($5.9)	($7.0)	($20.2)	($26.8)	($32.8)
Reported EPS	**($2.10)**	**($0.37)**	**($0.51)**	**($0.70)**	**($0.83)**	**($2.41)**	**($3.05)**	**($2.73)**
Weighted Shares Outstanding	4.9	8.3	8.3	8.4	8.4	8.4	8.8	12.0

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

HISTORICAL STOCK PRICE



Source: Zacks Small Cap Research

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