

Virios Therapeutics, Inc.

(VIRI-NASDAQ)

VIRI: Testing Combination Antiviral Therapy to Treat Long COVID...

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 (03/21/22) **\$5.63**
Valuation **\$22.00**

OUTLOOK

On February 28, 2022, Virios Therapeutics, Inc. (VIRI) announced a research collaboration with the Bateman Horne Center (BHC) to study the effect of combination antiviral therapy for the treatment of Long COVID. Approximately 30% of COVID patients experience Long COVID, which results in the presence of various symptoms for weeks to months following a SARS-CoV-2 infection. The most commonly reported symptoms are fatigue, dyspnea, joint pain, and chest pain. SARS-CoV-2 is known to suppress the immune system, thus one theory on the cause of Long COVID is the reemergence of a dormant virus, including those in the herpes family. Virios is providing BHC with an unrestricted grant for an investigator-sponsored study to test the combination therapy IMC-2, Virios' second development candidate, in Long COVID patients. We anticipate the study initiating in 2Q22 and results to be available in 1H23.

SUMMARY DATA

52-Week High **\$6.95**
52-Week Low **\$4.07**
One-Year Return (%) **-1.75**
Beta **-1.69**
Average Daily Volume (sh) **18,504**

Shares Outstanding (mil) **8**
Market Capitalization (\$mil) **\$47**
Short Interest Ratio (days) **N/A**
Institutional Ownership (%) **12**
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 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	-\$0.52 E	-\$0.52 E	-\$0.52 E	-\$0.51 E	-\$2.06 E
2023					-\$1.94 E
2024					-\$2.16 E

WHAT'S NEW

Business Update

Testing Combination Antiviral Therapy for the Treatment of Long COVID

On February 28, 2022, Virios Therapeutics, Inc. (VIRI) [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 planned trial with BHC 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](#)).

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. With an expected start in the second quarter of 2022, 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), fibromyalgia (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.

Update on Phase 2b FORTRESS Trial

Virios 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.

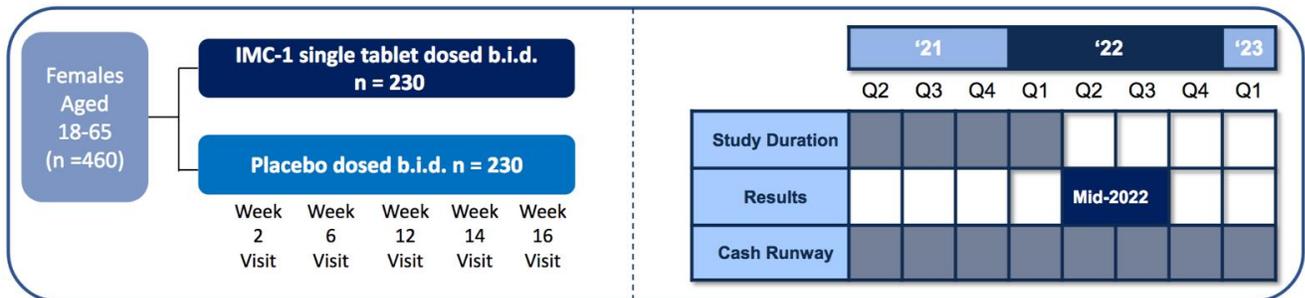
Primary Endpoint: Reduction in pain as measured by NRS 24 Hour Recall via daily electronic diary

Secondary Endpoints: Fatigue, sleep, global health, and patient functionality

FM Diagnosis using 2016 ACR criteria

IMC-1 Fixed Dose Tablet Dosed Twice Daily: 675mg famciclovir + 180mg celecoxib

Daily Assessments: 16 Weeks



Source: Virios Therapeutics, Inc.

During the fourth quarter conference call update, management indicated that the study is on pace to be fully enrolled by mid-April. We anticipate topline results from the trial in the third quarter of 2022.

Financial Update

On March 17, 2022, Virios announced financial results for the fourth quarter and fully year 2022. As expected, the company did not report any revenues for the fourth quarter or full year 2021. R&D expenses for the three months ending December 31, 2021 were \$2.9 million compared to \$0.03 million for the fourth quarter of 2020. The increase was primarily due to increased expenses for clinical trials, toxicology studies, and drug development and manufacturing. G&A expenses for the fourth quarter of 2021 were \$1.3 million compared to \$6.4 million for the fourth quarter of 2020. The decrease was primarily due to IPO-related expenses occurred in 2020, including non-cash share-based compensation expense of \$5.4 million.

For 2021, R&D expenses were \$10.8 million, compared to \$0.2 million for 2020. The increase was primarily due to expenses for the FORTRESS clinical trial, the chronic toxicology program, and drug development and manufacturing costs. G&A expenses for 2021 were \$4.8 million compared to \$9.8 million in 2020. The decrease was primarily due to IPO-related expenses in 2020, including non-cash equity and share-based compensation of \$7.4 million.

As of December 31, 2021, Virios had approximately \$14.0 million in cash and cash equivalents. We estimate the company has sufficient capital to fund operations through the end of the first quarter of 2023. As of March 15, 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

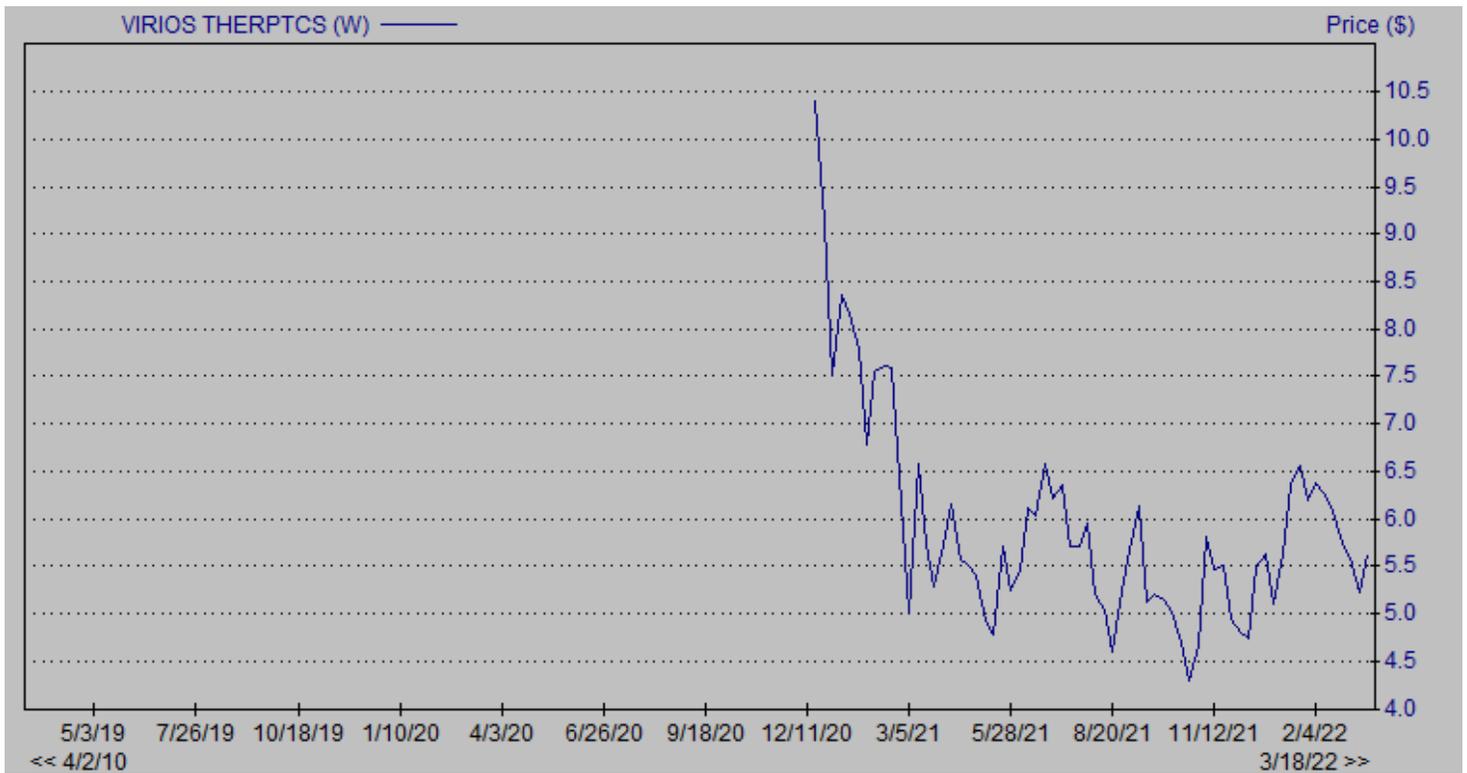
We're glad to see the company expanding its pipeline through the Long COVID collaboration with the Bateman Horne Center and we'll be very interested in the results of that study in the first half of 2023. In the meantime, we anticipate hearing about the full enrollment of the FORTRESS study in the next month or so, with topline results from that study anticipated in the third quarter of 2022. With no changes to the model, our valuation remains at \$22.

PROJECTED FINANCIALS

Virios Therapeutics, Inc.	2021 A	Q1 E	Q2 E	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							
CoGS	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
Product Gross Margin	-	-	-	-	-	-	-	-
R&D	\$10.8	\$3.0	\$3.0	\$3.0	\$3.0	\$12.0	\$14.0	\$16.0
SG&A	\$4.8	\$1.3	\$1.3	\$1.3	\$1.3	\$5.2	\$5.5	\$5.7
Operating Income	(\$15.6)	(\$4.3)	(\$4.3)	(\$4.3)	(\$4.3)	(\$17.2)	(\$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)	(\$4.3)	(\$4.3)	(\$4.3)	(\$4.3)	(\$17.2)	(\$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)	(\$4.3)	(\$4.3)	(\$4.3)	(\$4.3)	(\$17.2)	(\$19.4)	(\$21.6)
Reported EPS	(\$1.92)	(\$0.52)	(\$0.52)	(\$0.52)	(\$0.51)	(\$2.06)	(\$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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