Zacks Small-Cap Research
Sponsored – Impartial - Comprehensive

November 15, 2021
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: Filed IND for IMC-1 in Irritable Bowel Syndrome…

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 (11/15/21)	$5.48
Valuation	**$22.00**

OUTLOOK

On November 11, 2021, Virios Therapeutics, Inc. (VIRI) announced financial results for the third quarter of 2021 and provided a business update. The company is currently conducting the Phase 2b FORTRESS trial of its lead compound, IMC-1. Thus far, over 200 patients have been enrolled in the trial and we anticipate topline results from the trial in the third quarter of 2022.

The company also announced it has filed an Investigational New Drug (IND) application with the FDA to explore the potential of IMC-1 in patients with irritable bowel syndrome (IBS). Virios previously presented data showing replicating HSV-1 in GI tissue biopsy samples from patients with a chronic GI disorder, thus supporting the use of IMC-1 in this patient population.

SUMMARY DATA

52-Week High	**$16.71**
52-Week Low	**$4.07**
One-Year Return (%)	**N/A**
Beta	**N/A**
Average Daily Volume (sh)	**40,499**
Shares Outstanding (mil)	**8**
Market Capitalization ($mil)	**$46**
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)
2020	0 A	0 A	0 A	0 A	0 A
2021	0 A	0 A	0 A	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	-$0.49 A	-$0.83 E	-$2.21 E
2022					-$3.05 E
2023					-$2.73 E

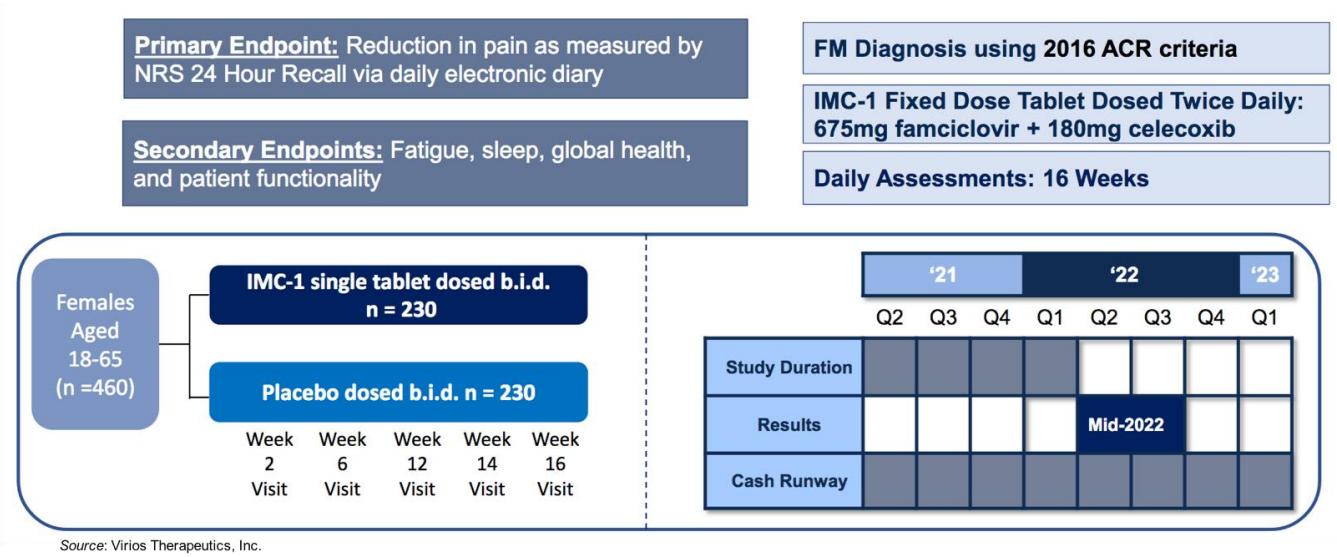
© Copyright 2021, Zacks Investment Research. All Rights Reserved.

WHAT'S NEW

Business Update

Update on 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 third quarter conference call update, management indicated that over 200 patients have been randomized into the trial thus far. In addition, as of now there has been no effect on enrollment due to the ongoing COVID-19 pandemic 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 anticipate topline results from the trial in the third quarter of 2022.

IMC-1 to be Tested as Treatment for IBS

During the third quarter conference call, Virios management announced that the company has filed an investigational new drug (IND) application with the FDA in order to test IMC-1 as a treatment for irritable bowel syndrome (IBS).

IBS is a chronic functional bowel disorder that is characterized by recurrent abdominal pain, often accompanied by bloating, related to defecation or in association with a change in stool frequency or form (Mearin *et al*., 2016). The condition negatively affects the quality of life, with one survey showing that patients would gladly trade 10-15 years of life expectancy for instant release from the disease (Canavan *et al*., 2014). More women than men are affected by IBS and the population prevalence ranges from 7-16% in the U.S. (Lovell *et al*., 2012). It is estimated that IBS has direct costs of >$1 billion in the U.S., thus finding effective treatments is important for decreasing the societal and economic impacts of the disease.

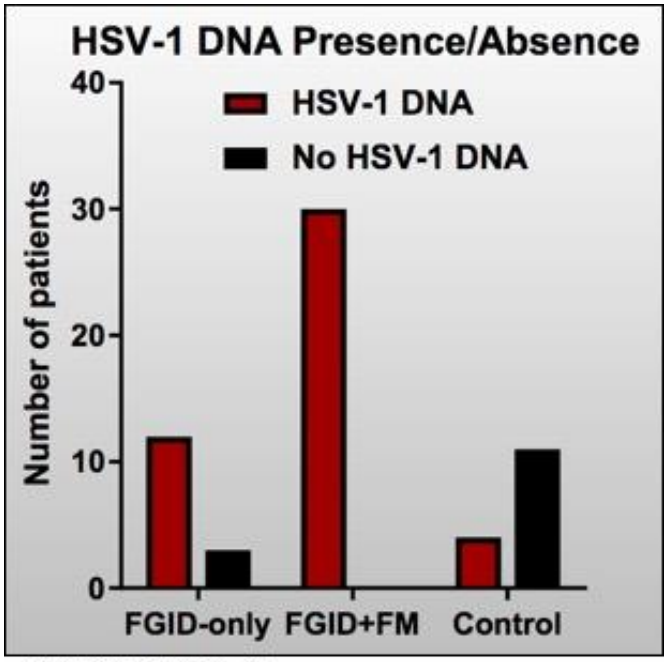
Various treatment approaches exist for IBS, including dietary changes, antispasmodic agents, antibiotics, probiotics, anti-inflammatory drugs, and antidepressants. Different prescription options include:

- Viberzi (eluxadoline), which was approved 2015 for IBS with diarrhea and had 2020 revenues of $184 million (EvaluatePharma).

- Xifaxan 550 (rifaximin), which was approved in 2015 for IBS with diarrhea and had 2020 revenues of $767 million (EvalutePharma).

- Linzess (linaclotide), which was approved in 2012 for IBS with constipation and had 2020 revenues of $444 million (EvaluatePharma).

None of the treatments listed above impacts the root cause of the disease, which Virios believes may be due to reactivated HSV-1 and the company has preliminary evidence to support this hypothesis. 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), which includes IBS, 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.

The company anticipates feedback on the IND for IBS before the end of 2021 or early in 2022, which could lead to a clinical trial getting underway in mid-2022. The trial will likely be similar in size to the Phase 2a trial of IMC-1 in fibromyalgia, which had approximately 140 patients. Data from the trial could be available in the first half of 2023.

Financial Update

On November 11, 2021, Virios announced financial results for the third quarter of 2021. As expected, the company did not report any revenues for the third quarter of 2021. R&D expenses for the three months ending September 30, 2021 were $3.0 million compared to $0.1 million for the third quarter of 2020. The increase was primarily due to increased expenses for clinical trials, toxicology studiesand drug development and manufacturing. G&A expenses increased were $1.1 million for the third quarter of 2021 compared to $2.5 million for the third quarter of 2020. The decrease was primarily due to compensation expense recognized in 2020 for the issuance of membership interests to Virios' founder offset by increased costs associated with being a public company.

As of September 30, 2021, Virios had approximately $19.2 million in cash and cash equivalents. We estimate the company has sufficient capital to fund operations through the end of 2022. As of November 11, 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

Everything seems to be going according to plan thus far for the Phase 2b FORTRESS trial and we estimate that topline results will be available in the third quarter of 2022. With approximately $19 million in cash and cash equivalents the company is sufficiently capitalized to the end of 2022, and importantly through the data readout for the FORTRESS trial.

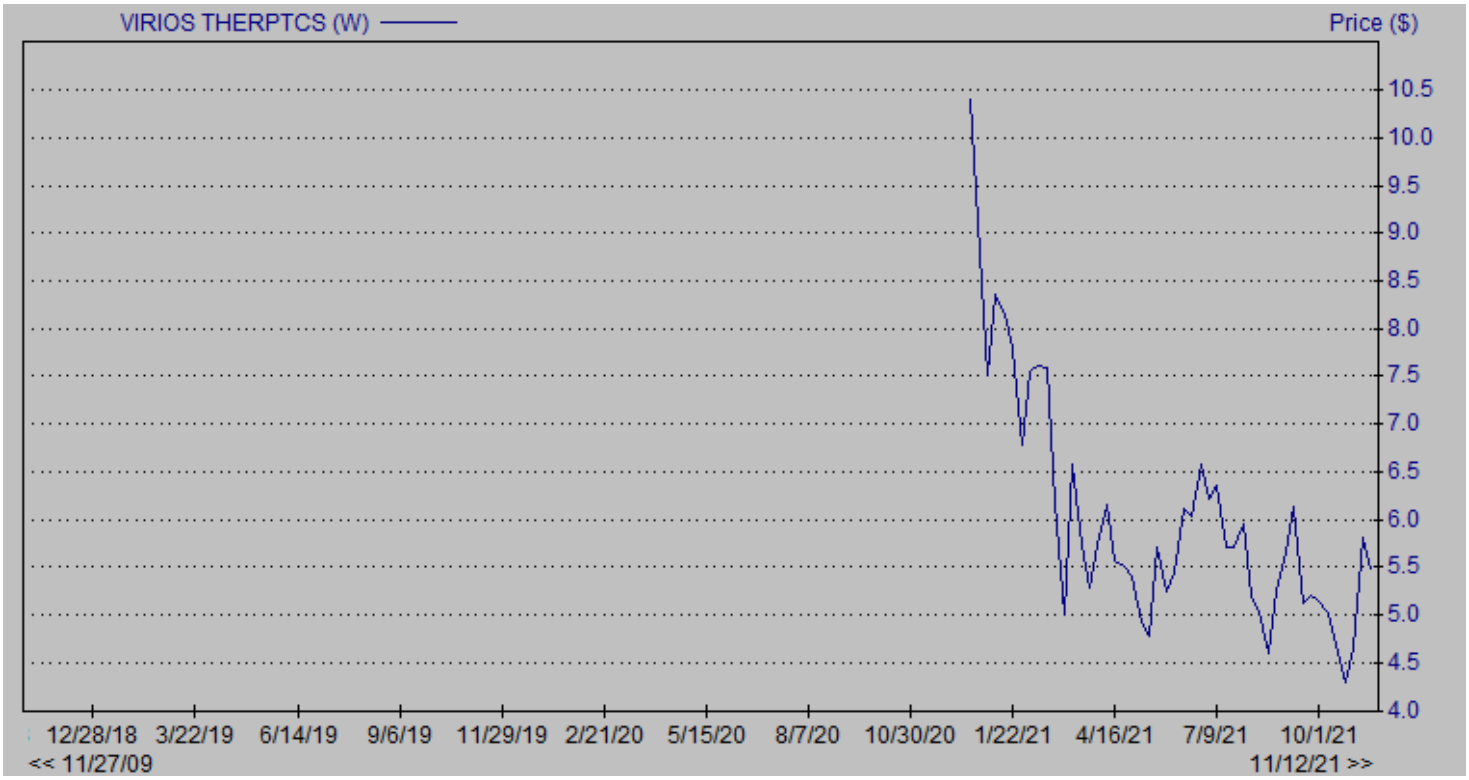
We like the decision by management to expand the potential market opportunity for IMC-1 into IBS, particularly given the data showing that HSV-1 activation is seen in those patients. Patients suffering from IBS need additional effective treatment options and we look forward to the initiation of the clinical trial in 2022. We had previously included additional indications for IMC-1 in our model, thus our valuation remains at $22.

PROJECTED FINANCIALS

Virios Therapeutics, Inc.	2020 A	Q1 A	Q2 A	Q3 A	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	$1.2	$3.0	$6.6	$12.0	$13.0
Operating Income	($10.0)	($3.1)	($4.3)	($4.1)	($7.0)	($18.5)	($27.0)	($33.0)
Operating Margin	-	-	-	-	-	-	-	-
Interest & Other Income	($0.3)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.2	$0.2
Pre-Tax Income	($10.3)	($3.1)	($4.3)	($4.1)	($7.0)	($18.4)	($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)	($4.1)	($7.0)	($18.4)	($26.8)	($32.8)
Reported EPS	**($2.10)**	**($0.37)**	**($0.51)**	**($0.49)**	**($0.83)**	**($2.21)**	**($3.05)**	**($2.73)**
Weighted Shares Outstanding	4.9	8.3	8.3	8.3	8.4	8.3	8.8	12.0

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

HISTORICAL STOCK PRICE



Source: Zacks Small Cap Research

DISCLOSURES

The following disclosures relate to relationships between Zacks Small-Cap Research ("Zacks SCR"), a division of Zacks Investment Research ("ZIR"), and the issuers covered by the Zacks SCR Analysts in the Small-Cap Universe.

ANALYST DISCLOSURES

I, David Bautz, PhD, hereby certify that the view expressed in this research report accurately reflect my personal views about the subject securities and issuers. I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the recommendations or views expressed in this research report. I believe the information used for the creation of this report has been obtained from sources I considered to be reliable, but I can neither guarantee nor represent the completeness or accuracy of the information herewith. Such information and the opinions expressed are subject to change without notice.

INVESTMENT BANKING AND FEES FOR SERVICES

Zacks SCR does not provide investment banking services nor has it received compensation for investment banking services from the issuers of the securities covered in this report or article.
Zacks SCR has received compensation from the issuer directly, from an investment manager, or from an investor relations consulting firm engaged by the issuer for providing non-investment banking services to this issuer and expects to receive additional compensation for such non-investment banking services provided to this issuer. The non-investment banking services provided to the issuer includes the preparation of this report, investor relations services, investment software, financial database analysis, organization of non-deal road shows, and attendance fees for conferences sponsored or co-sponsored by Zacks SCR. The fees for these services vary on a per-client basis and are subject to the number and types of services contracted. Fees typically range between ten thousand and fifty thousand dollars per annum. Details of fees paid by this issuer are available upon request.

POLICY DISCLOSURES

This report provides an objective valuation of the issuer today and expected valuations of the issuer at various future dates based on applying standard investment valuation methodologies to the revenue and EPS forecasts made by the SCR Analyst of the issuer's business.
SCR Analysts are restricted from holding or trading securities in the issuers that they cover. ZIR and Zacks SCR do not make a market in any security followed by SCR nor do they act as dealers in these securities. Each Zacks SCR Analyst has full discretion over the valuation of the issuer included in this report based on his or her own due diligence. SCR Analysts are paid based on the number of companies they cover. SCR Analyst compensation is not, was not, nor will be, directly or indirectly, related to the specific valuations or views expressed in any report or article.

ADDITIONAL INFORMATION

Additional information is available upon request. Zacks SCR reports and articles are based on data obtained from sources that it believes to be reliable, but are not guaranteed to be accurate nor do they purport to be complete. Because of individual financial or investment objectives and/or financial circumstances, this report or article should not be construed as advice designed to meet the particular investment needs of any investor. Investing involves risk. Any opinions expressed by Zacks SCR Analysts are subject to change without notice. Reports or articles or tweets are not to be construed as an offer or solicitation of an offer to buy or sell the securities herein mentioned.

CANADIAN COVERAGE

This research report is a product of Zacks SCR and prepared by a research analyst who is employed by or is a consultant to Zacks SCR. The research analyst preparing the research report is resident outside of Canada, and is not an associated person of any Canadian registered adviser and/or dealer. Therefore, the analyst is not subject to supervision by a Canadian registered adviser and/or dealer, and is not required to satisfy the regulatory licensing requirements of any Canadian provincial securities regulators, the Investment Industry Regulatory Organization of Canada and is not required to otherwise comply with Canadian rules or regulations.