

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, D.C. 20549

FORM 8-K

**CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934**

Date of Report (Date of earliest event reported): **September 19, 2022**

VIRIOS THERAPEUTICS, INC.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or other jurisdiction
of incorporation)

001-39811
(Commission
File Number)

85-4314201
(IRS Employer
Identification No.)

44 Milton Avenue
Alpharetta, GA
(Address of principal executive offices)

30009
(Zip Code)

Registrant's telephone number, including area code: **(866) 620-8655**

(Former name or former address, if changed since last report): Not Applicable

Securities registered pursuant to Section 12(b) of the Act:

| Title of each class | Trading Symbol(s) | Name of each exchange on which registered |
|----------------------------------|-------------------|---|
| Common Stock, par value \$0.0001 | VIRI | Nasdaq Capital Market |

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 7.01 Regulation FD Disclosure.

On September 19, 2022, Virios Therapeutics, Inc. (the “Company”) issued a press release relating to the announcement described in Item 8.01 below. A copy of the press release is included as Exhibit 99.1 to this Current Report on Form 8-K and is hereby incorporated by reference into this Item 7.01.

On September 19, 2022, the Company posted a presentation to its website that may be used by the Company from time to time with investors, analysts, collaborators, vendors or other third parties. A copy of the presentation is furnished as Exhibit 99.2.

The information in this Item 7.01, including the attached exhibits, is furnished solely pursuant to Item 7.01 of Form 8-K. Consequently, such information is not deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, or otherwise subject to the liabilities of that section. Further, the information in this Item 7.01, including the exhibits, shall not be deemed to be incorporated by reference into the filings of the registrant under the Securities Act of 1933.

Item 8.01 Other Events

On September 19, 2022, the Company announced top-line results from its FORTRESS (Fibromyalgia Outcome Research Trial Evaluating Synergistic Suppression of Herpes Simplex Virus-1) study of oral IMC-1 for the treatment of fibromyalgia.

Overall, the FORTRESS study 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).

However, analysis of the data suggests a bifurcation of response based on the timing of patient enrollment in the FORTRESS trial. During the first half of the trial (June 2021 to November 2021), for the patients who were enrolled (n=208) when the Delta variant of COVID-19 was the dominant strain in the U.S., IMC-1 demonstrated no improvement versus placebo-treated patients. Conversely, during the second half of the trial (November 2021 to April 2022), for the patients who were enrolled (n=214) when vaccination rates improved and the less severe Omicron variant of COVID-19 became the dominant U.S. strain, IMC-1-treated patients demonstrated a statistically significant improvement on the primary pain reduction endpoint (p=0.03) at Week 14, as well as a statistically significant improvement in the key secondary PROMIS Fatigue assessment (p=0.006) and the Fibromyalgia Impact Questionnaire-Revised (FIQR) symptoms domain score (p=0.015).

IMC-1 was well-tolerated overall, with only 4.6% of IMC-1 treated patients dropping out due to adverse events, as compared with 8.1% of placebo treated patients. No adverse event category in the IMC-1 group exceeded a 4% rate with the exception of COVID-19 infection. Overall discontinuations were 18.5% in the IMC-1 treated group versus 23% in the placebo treated group. Patients in the FORTRESS trial were randomized one-to-one to either IMC-1 or placebo and patient background demographics and baseline pain scores were well matched.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

| Exhibit Number | Description |
|-----------------------|--|
| 99.1 | Press Release of the Company, dated September 19, 2022 (furnished herewith). |
| 99.2 | Presentation dated September 19, 2022 (furnished herewith). |
| 104 | Cover Page Interactive Data File (formatted in Inline XBRL and contained in Exhibit 101) |

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

VIRIOS THERAPEUTICS, INC.

By: /s/ Angela Walsh
Name: Angela Walsh
Title: Senior Vice President of Finance and Corporate Secretary

September 19, 2022



Virios Therapeutics Announces Top-Line Results from Phase 2b Study of IMC-1 in Fibromyalgia

ATLANTA, Ga., September 19, 2022 -Virios Therapeutics, Inc. (Nasdaq: **VIRI**), a development-stage biotechnology company focused on advancing novel, combination antiviral therapies to treat debilitating chronic diseases, including fibromyalgia ("FM"), today announced topline results from its FORTRESS (Fibromyalgia Outcome Research Trial Evaluating Synergistic Suppression of Herpes Simplex Virus-1 ("HSV-1")) study of oral IMC-1 for the treatment of FM.

Overall, the FORTRESS study 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 ($p=0.302$). However, analysis of the data suggests a bifurcation of response based on the timing of patient enrollment in the FORTRESS trial. During the first half of the trial (June 2021 to November 2021), for the patients who were enrolled ($n=208$) when the Delta variant of COVID-19 was the dominant strain in the U.S., IMC-1 demonstrated no improvement versus placebo-treated patients. Conversely, during the second half of the trial (November 2021 to April 2022), for the patients who were enrolled ($n=214$) when vaccination rates improved and the less severe Omicron variant of COVID-19 became the dominant U.S. strain, IMC-1-treated patients demonstrated a statistically significant improvement on the primary pain reduction endpoint ($p=0.03$) at Week 14, as well as a statistically significant improvement in the key secondary PROMIS Fatigue assessment ($p=0.006$) and the Fibromyalgia Impact Questionnaire-Revised (FIQR) symptoms domain score ($p=0.015$).

IMC-1 was well-tolerated overall, with only 4.6% of IMC-1 treated patients dropping out due to adverse events, as compared with 8.1% of placebo treated patients. No adverse event category in the IMC-1 group exceeded a 4% rate with the exception of COVID-19 infection. Overall discontinuations were 18.5% in the IMC-1 treated group versus 23% in the placebo treated group. Patients in the FORTRESS trial were randomized one-to-one to either IMC-1 or placebo and patient background demographics and baseline pain scores were well matched.

"We were surprised by the overall primary efficacy result from this study, as we believe this approach continues to have scientific validity and the potential to provide FM patients with a much-needed, well-tolerated therapeutic option. We believe the interplay between different COVID-19 strains and herpes virus activation may be contributing to the differential response we observed in patients enrolled in 2021 versus 2022," stated Greg Duncan, Chairman and CEO of Virios Therapeutics. "Our team and outside advisors are in the process of further analyzing the



FORTRESS data, and we will provide an update on our overall plan to advance the development of IMC-1 as soon as possible.”

“Overall, the efficacy data from this trial were not what we had expected,” said R. Michael Gendreau, M.D., Ph.D., Chief Medical Officer of Virios Therapeutics. “We will continue to explore IMC-1’s potential as a viable FM treatment option. We would like to thank all of the investigators and patients who participated in FORTRESS for their support of this important research.”

Study Overview

The FORTRESS study was a double-blind, placebo-controlled safety and efficacy study of IMC-1 antiviral combination therapy. The final enrollment included 425 female patients, aged 18 to 65, all of whom were diagnosed with FM using the 2016 American College of Rheumatology diagnostic criteria for FM. Study participants were randomized 1-to-1 to either IMC-1 or matching placebo. Three patients were randomized but no data were collected, hence are excluded from our statistical analysis plan. The prespecified primary endpoint for the FORTRESS study was reduction in pain over time as measured by the change from baseline to the Week 14 endpoint in the diary Numerical Rating Scale (NRS) weekly average of daily self-reported average pain severity scores. Scores range from 0 to 10 where a higher score means worse outcome. Pain was recorded in an electronic diary system that patients used at home on a daily basis. In addition to assessing FM patients’ pain reduction, the study also assessed IMC-1’s ability to improve symptoms of fatigue and sleep disturbance, and measured improvements in overall global health status and patient function.

The Virios Therapeutics team received unblinded data relating to the FORTRESS study on Friday, September 16, 2022.

Conference Call

Virios Therapeutics will host a conference call and live webcast to discuss the FORTRESS study results today, Monday, September 19th, at 8:30 a.m. Eastern Time. The live webcast can be accessed at <https://www.webcaster4.com/Webcast/Page/2639/46330>. To access the conference call, U.S. participants may call (888) 506-0062 and international participants may call (973) 528-0011. The conference ID number is 449989. A live webcast and replay of the call will also be available on the Virios Therapeutics, Inc. website at www.virios.com. A telephone replay of the conference call will be available until Monday, October 3, 2022. To access this replay, U.S. participants may call (877) 481-4010 and international participants may call (919) 882-2331. The conference ID number for the replay is 46330.



About Virios Therapeutics

Virios Therapeutics (Nasdaq: VIRI) is a development-stage biotechnology company focused on advancing novel antiviral therapies to treat debilitating chronic diseases, such as fibromyalgia ("FM"). Immune responses related to the activation of tissue resident herpes have been postulated as a potential root cause triggering and/or sustaining chronic illnesses such as FM, irritable bowel disease, chronic fatigue syndrome and other functional somatic syndromes, all of which are characterized by waxing and waning symptoms with no obvious etiology. Our lead development candidate ("IMC-1") is a novel, proprietary, fixed dose combination of famciclovir and celecoxib designed to synergistically suppress herpes virus replication, with the end goal of reducing virally promoted disease symptoms. IMC-1 has been granted fast track designation by the FDA.

The Company is pursuing a second development candidate, IMC-2 (valacyclovir and celecoxib), as a potential treatment for managing the fatigue, sleep, attention, pain, autonomic function and anxiety associated with Long-COVID, otherwise known as Post-Acute Sequelae of COVID-19 (PASC). The Company has provided Bateman Horne Center ("BHC") with an unrestricted investigational grant to conduct this study. BHC is a non-profit, interdisciplinary Center of Excellence advancing the diagnosis and treatment of chronic fatigue disorders, FM, post-viral syndromes, and related comorbidities.

For more information, please visit www.virios.com.

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Forward-Looking Statements

Statements in this press release contain "forward-looking statements," within the meaning of the U.S. Private Securities Litigation Reform Act of 1995, that are subject to substantial risks and uncertainties. All statements, other than statements of historical fact, contained in this press release are forward-looking statements. Forward-looking statements contained in this press release may be identified by the use of words such as "anticipate," "believe," "contemplate," "could," "estimate," "expect," "intend," "seek," "may," "might," "plan," "potential," "predict,"



“project,” “suggest,” “target,” “aim,” “should,” “will,” “would,” or the negative of these words or other similar expressions, although not all forward-looking statements contain these words. Forward-looking statements are based on Virios Therapeutics’ current expectations and are subject to inherent uncertainties, risks and assumptions that are difficult to predict, including risks related to the completion, timing and results of current and future clinical studies relating to Virios Therapeutics’ product candidates. Further, certain forward-looking statements are based on assumptions as to future events that may not prove to be accurate. These and other risks and uncertainties are described more fully in the section titled “Risk Factors” in the Annual Report on Form 10-K for the year ended December 31, 2021, filed with the Securities and Exchange Commission. Forward-looking statements contained in this announcement are made as of this date, and Virios Therapeutics, Inc. undertakes no duty to update such information except as required under applicable law.

Contact:

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PCG Advisory

Kirin Smith

ksmith@pcgadvisory.com

FORTRESS STUDY SUMMARY

Topline Results
September 19, 2022

HSV-1 virus

VIREOS
Therapeutics

Forward Looking Statements

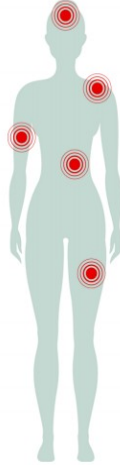
- Statements in this presentation contain "forward-looking statements" that are subject to substantial risks and uncertainties. Forward-looking statements contained in this presentation may be identified by the use of words such as "anticipate," "expect," "believe," "will," "may," "should," "estimate," "project," "outlook," "forecast" or other similar words, and include, without limitation, all statements other than those regarding historical facts, statements regarding Virios Therapeutics, Inc.'s expectations regarding our future financial or business performance, plans, prospects, trends or strategies, objectives of management, competition and other financial and business matters; the potential, safety, efficacy, and regulatory and clinical progress of our current and prospective product candidates, planned clinical trials and preclinical activities, and projected research and development costs; the estimated size of the market for our product candidates; and the timing and success of our development and commercialization of our anticipated product candidates and the market acceptance thereof. Forward-looking statements are based on our current expectations and are subject to inherent uncertainties, risks and assumptions that are difficult to predict. Further, certain forward-looking statements are based on assumptions as to future events that may not prove to be accurate. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including, but not limited to, the following: the ongoing effects of COVID-19 has adversely impacted and may continue to adversely impact our business, including our preclinical studies and clinical trials; our limited operating history, which may make it difficult to evaluate our current business and predict our future success and viability; we have and expect to continue to incur significant losses; our need for additional funding, which may not be available; our substantial dependence on the success of our lead product candidates; failure to identify additional product candidates and develop or commercialize marketable products; the early stage of our development efforts; potential unforeseen events during clinical trials could cause delays or other adverse consequences; risks relating to the regulatory approval process or ongoing regulatory obligations; our product candidates may cause serious adverse side effects; our reliance on third parties; effects of significant competition; the possibility of system failures or security breaches; risks relating to intellectual property; our ability to attract, retain and motivate qualified personnel; and significant costs as a result of operating as a public company. These and other risks and uncertainties are described more fully in the section titled "Risk Factors" in the Annual Report on Form 10-K for the year ended December 31, 2021 filed with the Securities and Exchange Commission ("SEC") and elsewhere in our filings and reports with the SEC. While we may elect to update these forward-looking statements at some point in the future, we assume no obligation to update or revise any forward-looking statements except to the extent required by applicable law. Although we believe the expectations reflected in such forward-looking statements are reasonable, we can give no assurance that such expectations will prove to be correct. Accordingly, readers are cautioned not to place undue reliance on these forward-looking statements. No representations or warranties (expressed or implied) are made about the accuracy of any such forward-looking statements.
- This presentation also contains estimates and other statistical data made by independent parties and by us relating to market size and other data about our industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such data and estimates. In addition, projections, assumptions and estimates of our future performance and the future performance of the markets in which we operate are necessarily subject to a high degree of uncertainty and risk. Neither we nor our affiliates, advisors or representatives makes any representation as to the accuracy or completeness of that data or undertake to update such data after the date of this presentation.
- You should read the documents that we have filed with the SEC for more complete information about us. We encourage you to read such documents in full for more detailed information on statistics, reports and clinical trials referenced in this presentation. You may access these documents for free by visiting EDGAR on the SEC website at <http://www.sec.gov>.

Fibromyalgia Disease Overview



Syndrome Characteristics

- American College of Rheumatology Estimates 2-4% of Population has FM
- Hallmark Characteristics are Widespread Chronic Pain and Severe Fatigue
 - Symptoms Present for ≥ 3 Months
- Other Symptoms May Include GI, Sleep, Mood Disorder and Headache
- Higher prevalence in females: 70%



Devastating Impact

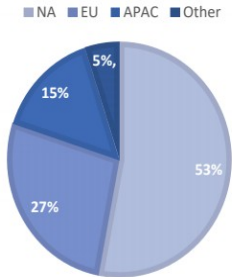
- Patients with FM > 3x Risk of Committing Suicide v. General Population
- High Healthcare Utilization
 - Avg 10 Office Visits/Year
- Significant Disability
 - One in two patients miss work
- Estimates Suggest as Many as 40% of FM Patients are Treated with Opioids

Sources: The Hidden Impact of Musculoskeletal Disorders on Americans, 4th edition; Berger et al *Clin Pract* 2007; White et al *J Occup Environ Med* 2008; Wolfe et al *Arthritis Care & Res* 2014; Fitzcharles et al *Am J Med* 2011; Robinson et al *Pain Medicine* 2012; Peng et al *Clin J Pain* 2015; Chad S Boomershine, MD, PhD, CPI, CPT, *Medscape*, 2022; *Verifjed Market Research*, FM Report 2021

The Global Fibromyalgia Market is Large but Dissatisfied, Poised for Growth if Better Therapeutic Options Emerge

Significant Global FM Commercial Opportunity

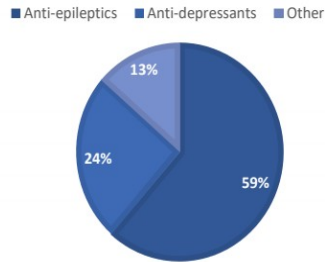
GLOBAL FM SALES BY REGION



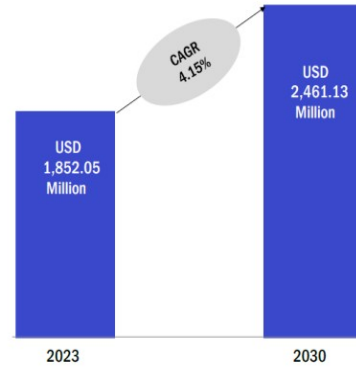
Source: Verified Market Research, FM Report, 2021

Anti-epileptics and Anti-depressants are Dominant Treatments

GLOBAL SALES BY THERAPEUTIC CLASS

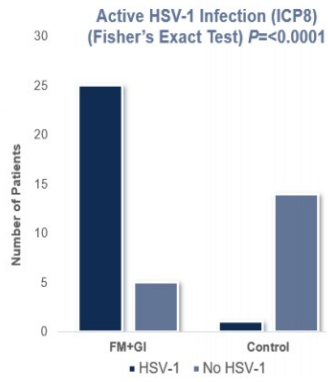


Global FM Market Estimated to Reach \$2.46B in 2030

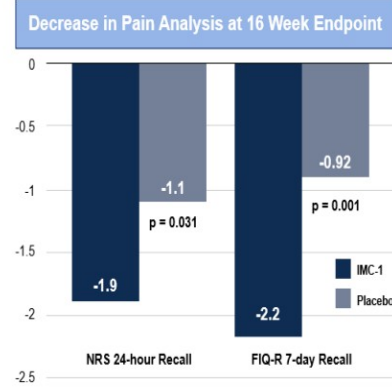


Purposeful Research Approach Focused on Herpes Virus Inhibition Demonstrates IMC-1 Clinical Potential in FM

GI Biopsy Study Confirms Herpes Infection in Somatic Syndrome Disorders



Phase 2a Clinical Study Identifies Potential of IMC-1



Source: C. Duffy, et al, *Infection*, 2022; W. Pridgen et al, *Journal of Pain* 2017; Virios Therapeutics, Inc, Data on File, 2022

FORTRESS Study Highlights

- ❖ Overall, IMC-1 did not achieve statistical significance on the primary efficacy endpoint of change from baseline to Week 14 in the weekly average of daily self-reported pain scores comparing IMC-1 and placebo (p=0.302)
- ❖ Bifurcation of response based on the timing of patient enrollment in the trial:
 - Cohort 1 Enrollment (June 2021-Nov 2nd 2021, n=208): Delta variant of COVID-19 was the dominant strain in the US, IMC-1 demonstrated no significant improvement versus placebo treated patients
 - Cohort 2 Enrollment (Nov 3rd 2021-Apr 15th 2022, n=214): Omicron variant of COVID-19 dominant, IMC-1 treated patients demonstrated statistically significant improvement on key outcome measures including:
 - The primary pain reduction endpoint (p=0.030)
 - Secondary outcome of PROMIS fatigue (p=0.006)
 - Key secondary Fibromyalgia Impact Questionnaire-Revised (FIQR) symptoms domain (p=0.015)
- ❖ IMC-1 was very well tolerated
 - Discontinuation due to adverse events occurred in only 4.6% of IMC-1 treated patients, as compared to 8.1% of placebo treated patients.
- ❖ Team is presently exploring best opportunities for development of IMC-1 going forward

FORTRESS Clinical Trial Design

Design Summary:

- 425 Female Patients Enrolled 18-65 Years of Age, 422 ITT population
- 1:1 IMC-1 (675mg famciclovir + 180mg celecoxib) vs Placebo, Dosed BID
- Double-blind, 41 US Research Centers
- Diagnosis of Fibromyalgia Using 2016 ACR Criteria

Primary Endpoints:
Reduction in Pain

Key Secondary Endpoints:
PGIC, FIQ-R Domains,
30% & 50% pain responder analyses

14 weeks of IMC-1 or Placebo Treatment, Followed by Two Week Placebo Washout for All Subjects

| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 |
|---------|---|---|---|---|---|---|---|---|---|----|----|----|----|----|----|----|
| IMC-1 | | | | | | | | | | | | | | | | |
| Placebo | | | | | | | | | | | | | | | | |

Prospectively Defined
Primary Endpoint Analysis



FORTRESS Disposition

| | Placebo | IMC-1 | Total |
|----------------------------|----------------|--------------|--------------|
| | (N=209) | (N=216) | (N=425) |
| Randomized | 209 (100.0%) | 216 (100.0%) | 425 (100.0%) |
| Completed | 161 (77.0%) | 176 (81.5%) | 337 (79.3%) |
| Discontinued Early | 48 (23.0%) | 40 (18.5%) | 88 (20.7%) |
| Reason for Discontinuation | | | |
| Adverse Event | 17 (8.1%) | 10 (4.6%) | 27 (6.4%) |
| Lost to follow-up | 6 (2.9%) | 7 (3.2%) | 13 (3.1%) |
| Lack of efficacy | 8 (3.8%) | 6 (2.8%) | 14 (3.3%) |
| Investigator decision | 2 (1.0%) | 0 (0.0%) | 2 (0.5%) |
| Withdrawal of consent | 12 (5.7%) | 12 (5.6%) | 24 (5.6%) |

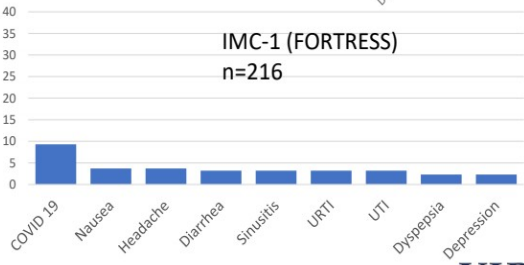
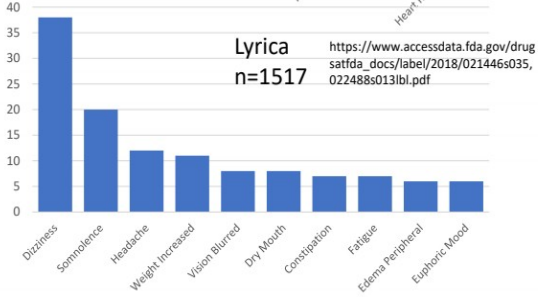
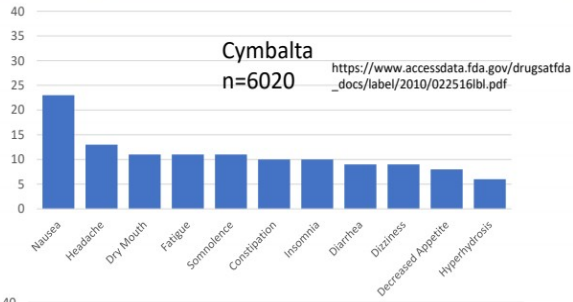
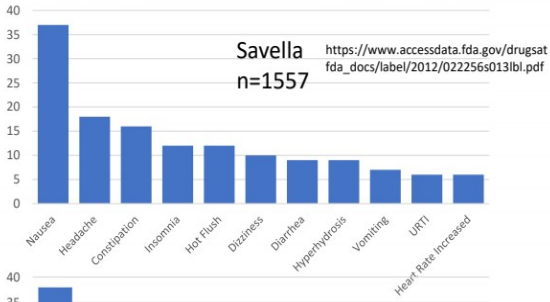
FORTRESS Adverse Events

| AEs in >2% of IMC-1 Patients | Placebo | IMC-1 | Total |
|-----------------------------------|-------------|-------------|-------------|
| Preferred Term | (N=208) | (N=216) | (N=424)* |
| | 110 (52.9%) | 121 (56.0%) | 231 (54.5%) |
| COVID-19 | 17 (8.2%) | 20 (9.3%) | 37 (8.7%) |
| Nausea | 4 (1.9%) | 8 (3.7%) | 12 (2.8%) |
| Headache | 12 (5.8%) | 8 (3.7%) | 20 (4.7%) |
| Sinusitis | 7 (3.4%) | 7 (3.2%) | 14 (3.3%) |
| Upper respiratory tract infection | 1 (0.5%) | 7 (3.2%) | 8 (1.9%) |
| Urinary tract infection | 10 (4.8%) | 7 (3.2%) | 17 (4.0%) |
| Diarrhoea | 7 (3.4%) | 7 (3.2%) | 14 (3.3%) |
| Dyspepsia | 3 (1.4%) | 5 (2.3%) | 8 (1.9%) |
| Depression | 2 (1.0%) | 5 (2.3%) | 7 (1.7%) |

* Note: safety population was n=424 due to one patient who was randomized but never received drug



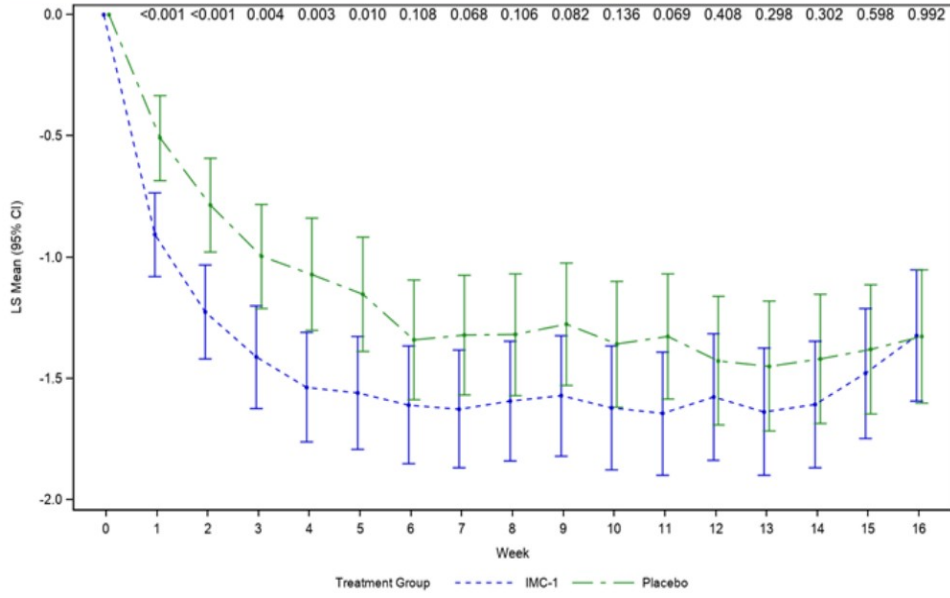
FM Treatment Tolerability: TEAEs > 5% from PIs*



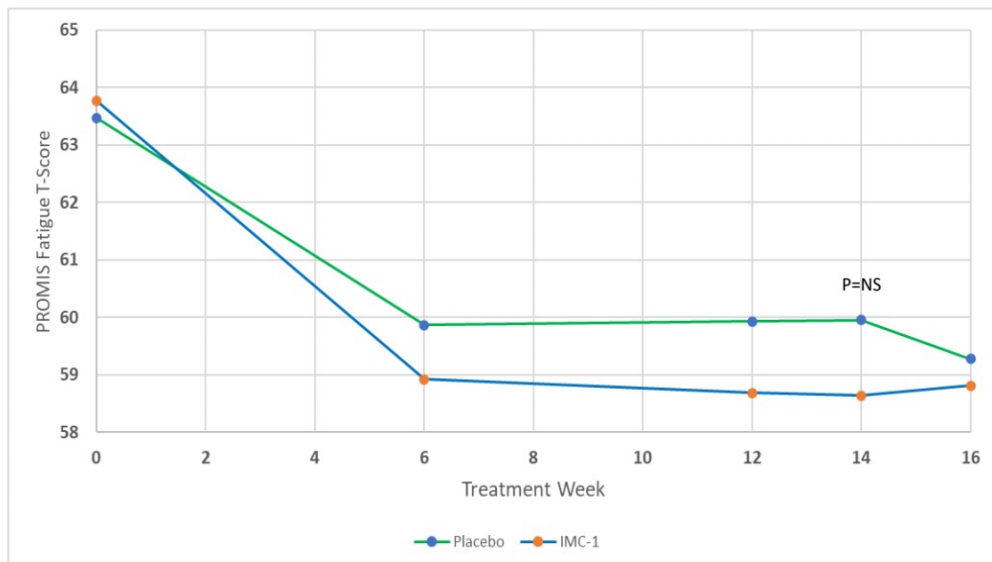
*Not a head to head comparison



Primary Endpoint: Diary Pain Improvement Over Time



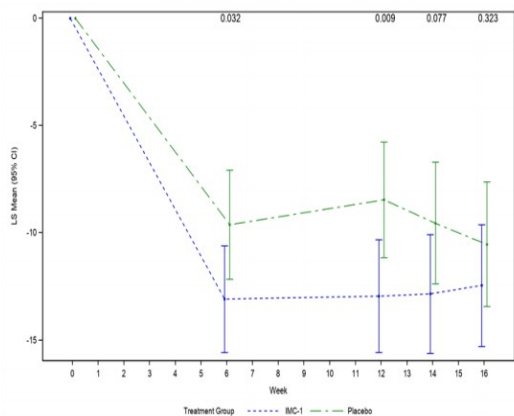
PROMIS Fatigue Improvement- Full Dataset



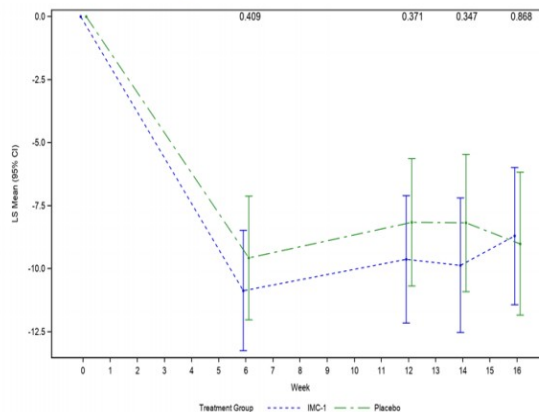
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FIQR Symptoms & Function Improvement

FIQR Symptom Domain



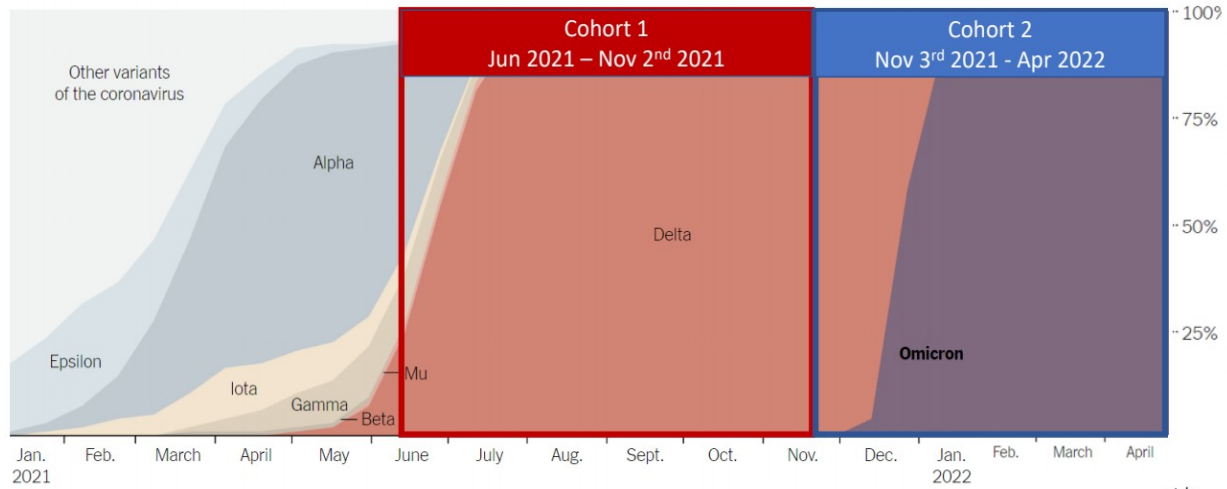
FIQR Function Domain



Enrollment Timing and COVID-19 Variants

Waves of Variants in the United States

Omicron has pushed aside Delta as the dominant variant in the United States.



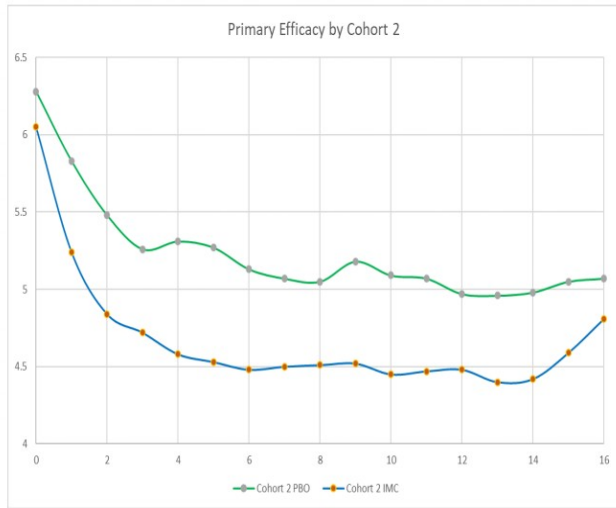
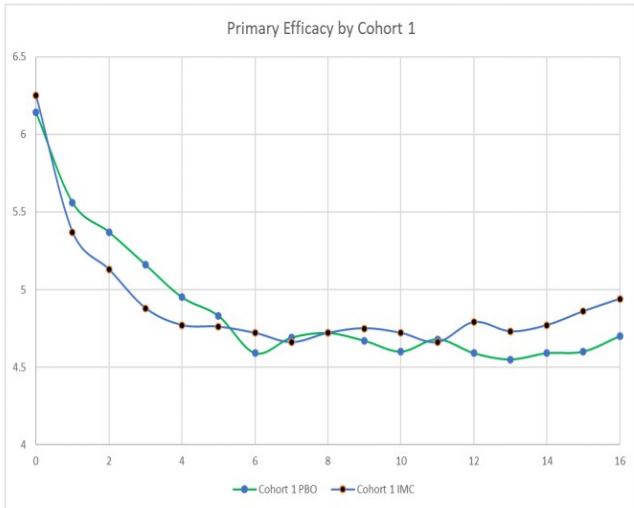
<https://www.nytimes.com/interactive/2021/health/coronavirus-variant-tracker.html>



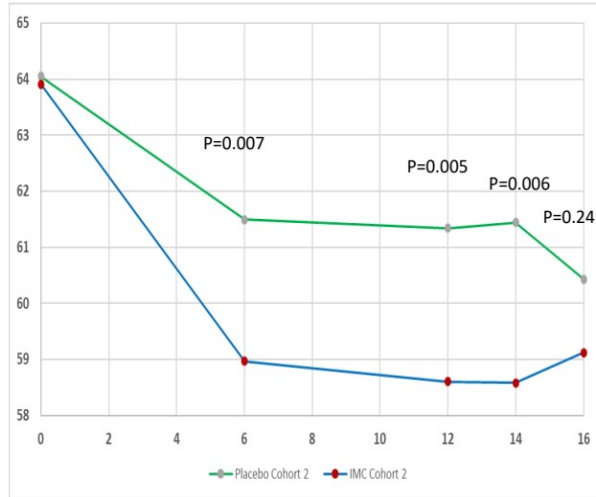
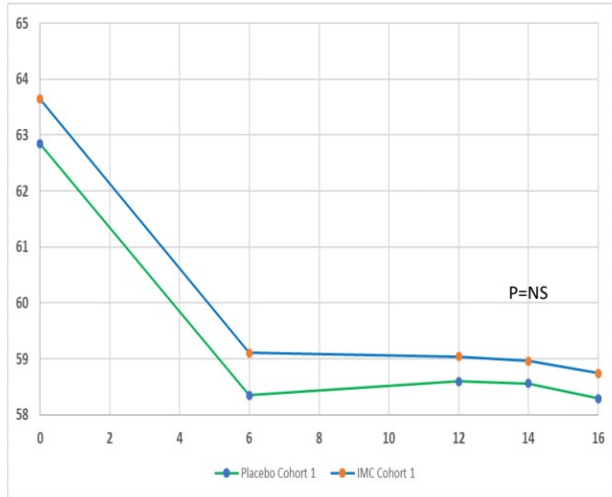
Cohort 1 Versus Cohort 2 Analyses

| Primary Endpoint | Enrollment Dates | Placebo Baseline | Placebo Week 14 | IMC-1 Baseline | IMC-1 Week 14 | CFB | P Value |
|-------------------|--|------------------|-----------------|----------------|---------------|------------|---------|
| Cohort 1 n=208 | June '21 - Nov 2 nd , '21 | 6.14 | 4.59 | 6.25 | 4.77 | 0.18 (PBO) | -0.484 |
| Cohort 2 n=214 | Nov 3 rd , '21 - April 15 th '22 | 6.28 | 4.98 | 6.05 | 4.42 | -0.56 | 0.030 |

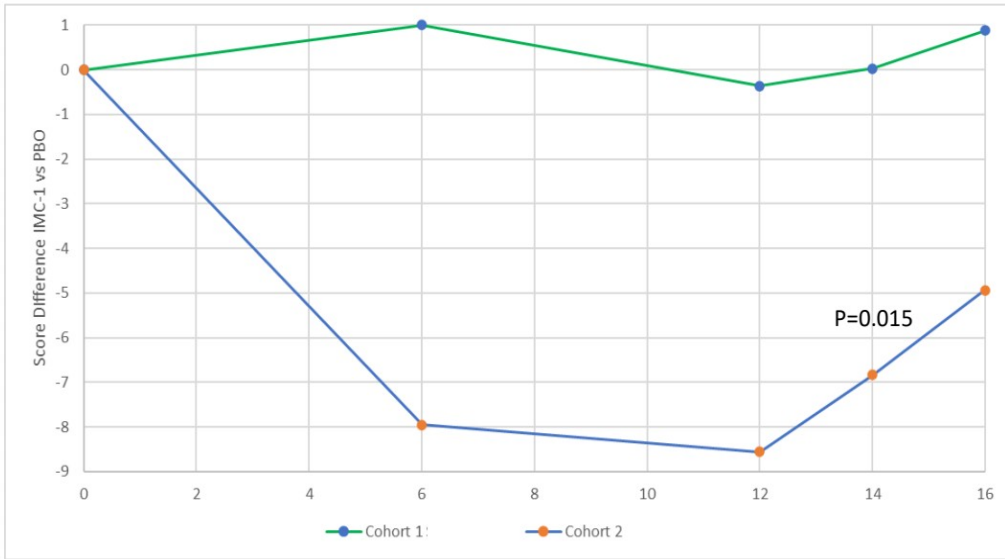
Primary Efficacy Daily Pain Score By Treatment Week in Cohorts 1 & 2



PROMIS Fatigue T-Score Improvement By Treatment Week For Cohorts 1 & 2

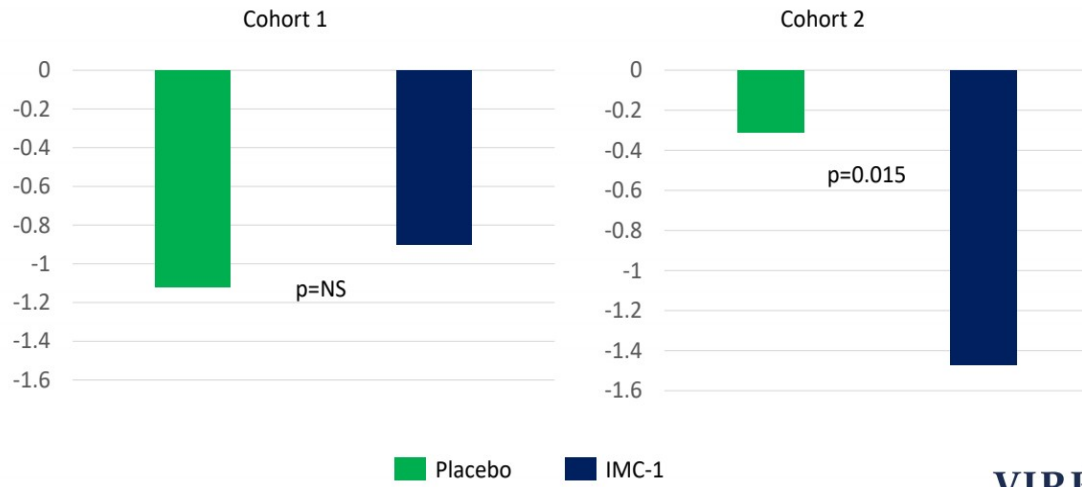


FIQR Symptom Domain Scores Over 16 Weeks of Treatment: IMC-1 vs. Placebo For Cohorts 1 & 2



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Mean Change in HADS Depression Score by Cohort at Week 14



FORTRESS Summary

- ❖ Virios management strongly believes this mechanism has potential to improve FM patient care
 - Positive Phase 2a clinical study results
 - IMC-1 in Cohort 2 delivered statistically significant improvement in FM patient pain, fatigue, depression and overall health status
 - IMC-1 in Cohort 2 efficacy results were consistent with the expected profile from previous Phase 2a study
 - The difference in results between Cohort 1 and Cohort 2 is highly unlikely due to chance
- ❖ We believe the excellent overall safety and tolerability profile observed in FORTRESS supports future product development
- ❖ Our ultimate goal is to get IMC-1 to market
- ❖ Our short-term plan is to engage with KOLs/BoD to better understand the Phase 2b data and design a forward development plan to maximize the potential of IMC-1



THANK YOU!

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HSV-1 virus

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