

**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): **November 16, 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.

On November 16, 2022, Virios Therapeutics, Inc. (the “Company”) will be posting 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 99.1.

The information in this Item 7.01, including the attached exhibit, 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 exhibit, shall not be deemed to be incorporated by reference into the filings of the registrant under the Securities Act of 1933.

Cautionary Statement Regarding Forward-Looking Information

This current report on Form 8-K contains “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 those of historical fact in this presentation and accompanying oral commentary are forward-looking statements. Forward-looking statements may be identified by terminology such as “believe,” “anticipate,” “plan,” “may,” “intend,” “will,” “should,” “expect,” “estimate,” “potential”, “outlook”, “forecast” and “continue” and similar expressions, including the negative of these words, but not all forward-looking statements contain these words. Forward-looking statements include, but are not limited to, statements regarding the Company’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: risks generally related to the completion, timing and results of current and future research or clinical studies relating to our product candidates; 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.

Item 9.01 Financial Statements and Exhibits.

(d) _____ Exhibits.

Exhibit Number	Description
99.1	Presentation dated November 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: SVP of Finance and Corporate Secretary

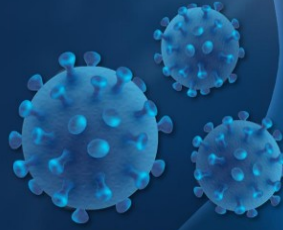
November 16, 2022



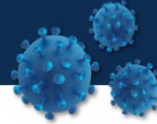
New Scientific Paradigm Exploring Herpes
Virus Activation as Potential Underlying
Cause of Fibromyalgia, Long COVID and
Other Chronic Conditions

Nasdaq: VIRI

November 2022

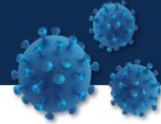


Forward Looking Statements



- 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>.

Proven Leadership Team with Extensive Experience in Drug Development and Commercialization



EXECUTIVE TEAM



Greg Duncan
Chairman & CEO



R. Michael Gendreau
MD, PhD CMO



Angela Walsh
SVP of Finance



Ralph Grosswald
SVP of Operations



DIRECTORS



Rich Whitley, MD

- Distinguished Professor, UAB
- Remdesivir was Originally Developed by Dr. Whitley's team at UAB
- DSMB Chair, Operation Warp Speed



Rick Keefer

- 30-year Pharma industry veteran with broad-based experience in leading commercial operations
- Executive roles at Pharmacia, Pfizer, Wyeth, Biorel and Publicis Health
- Seven-time winner of Pharma Voice's top 100 healthcare leaders



Abel De La Rosa, PhD

- Chairman, Co-Founder Anitos Therapeutics
- Led Bus Dev for Pharmasset acquisition by GILD for \$11.5 billion in 2012
- Leadership for Development Programs for the Treatment of HIV, Hepatitis B & C, including Sofosbuvir



Rick Burch

- 30 years at PFE including SVP
- VP and GM UCB Pharmaceuticals
- Former President of VIRI, Inc.
- Product launches include Lyrica & Celebrex



John Thomas, CPA

- CorMatrix Inc., MMedx Group, Inc., DARA BioSciences, GMP Companies
- MRI Interventions, EnterMed, Inc., Medicis Pharm Corp., CyRx Corp



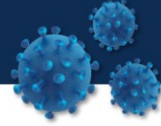
Skip Pridgen, MD
VIRI Founder

- Company Founder
- Board-certified surgeon practicing with Tuscaloosa Surgical Associates, P.C.
- Served as a physician and surgeon in the U.S. Navy

Pharma Brand Development & Commercialization Experience Includes Management of:

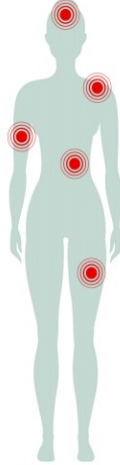


Fibromyalgia Disease Overview



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%

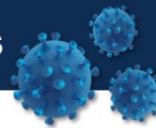


Devastating Impact

- Patients with FM > 3x Risk of Committing Suicide v. General Population
- High Healthcare Utilization
 - Avg 10 Office Visits/Year
- Significant Disability
- Estimates Suggest as Many as 40% of FM Patients are Treated with Opioids
- Only Three FDA Approved Medicines

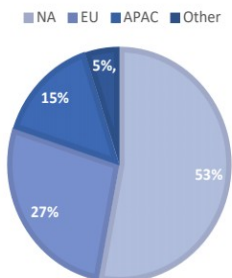
Sources: The Hidden Impact of Musculoskeletal Disorders on Americans, 4th edition; Berger et al *Clin Pract* 2007; White et al *J Occup Environ Med* 2008; Wolfe et al *Arthritis Care & Res* 2014; Fitzcharles et al *Am J Med* 2011; Robinson et al *Pain Medicine* 2012; Peng et al *Clin J Pain* 2015, Chad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

The Global Fibromyalgia Market is Large but Dissatisfied, Largely Due to Poor Tolerability of the Approved Medicines



Significant Global FM Commercial Opportunity

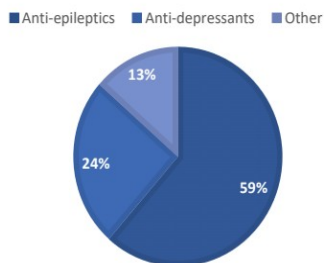
GLOBAL FM SALES BY REGION



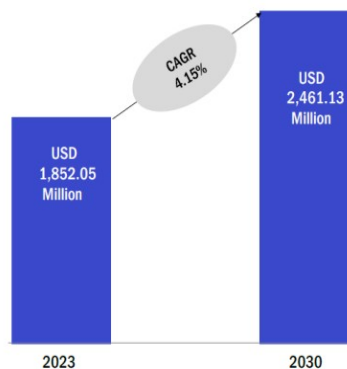
Source: Verified Market Research, FM Report, 2021

Anti-epileptics and Anti-depressants are Dominant Treatments

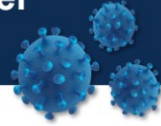
GLOBAL SALES BY THERAPEUTIC CLASS



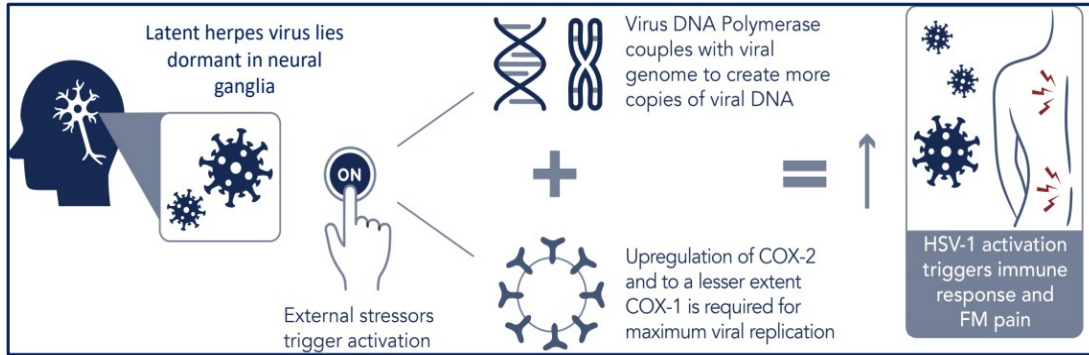
Global FM Market Estimated to Reach \$2.46B in 2030



Dormant Herpes Virus Reactivation Hypothesized to Trigger Dysfunctional Immune Response, Disease Symptoms

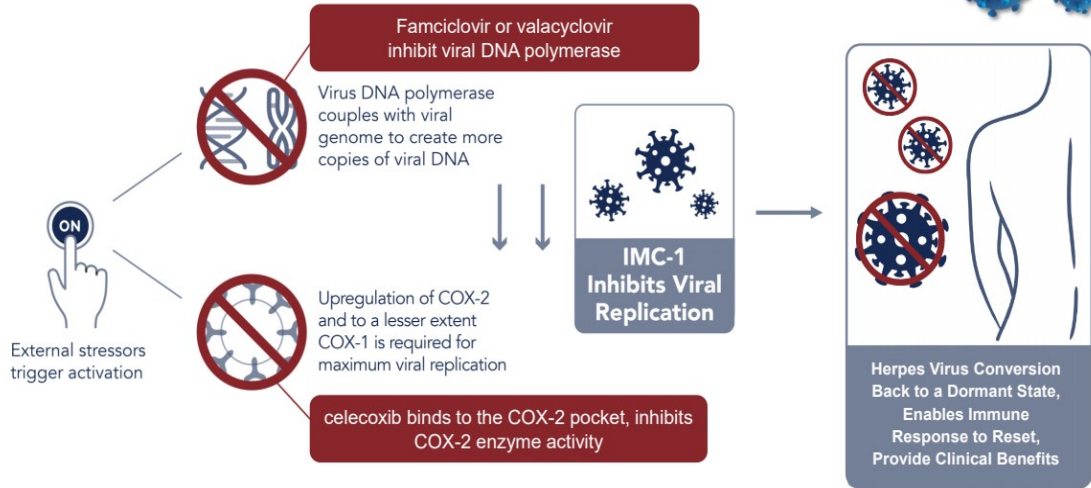


Herpes virus infection is life long and resident in peripheral neurons or immune system cells



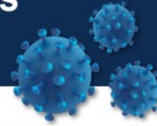
Source: P.A. Bond, *Medical Hypotheses*, 1993; R. A Vere Hodge and Y.-G. Cheng, *Antiviral Chemistry & Chemotherapy*, 1993; Kaufman et al, *IOVS*, 2005; Liu Y, et al, *Scientific World Journal*, 2014; Higaki S, et al *Current Eye Research*, 2009; Francisco Javier Ibarñez et al, *Frontiers in Microbiology*, 2018

Synergistic Antiviral Mechanism Serves as the Basis for Proposed FM Treatment Effect

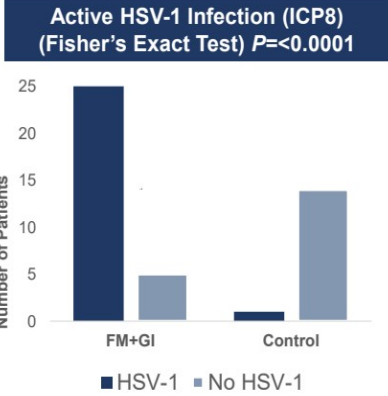


Source: P.A. Bond, *Medical Hypotheses*, 1993; R. A Vere Hodge and Y.-G. Cheng, *Antiviral Chemistry & Chemotherapy*, 1993; Liu Y, et al, *Scientific World Journal*, 2014; Higaki S, et al *Current Eye Research*, 2009; Francisco Javier Ibañez et al, *Frontiers in Microbiology*, 2018

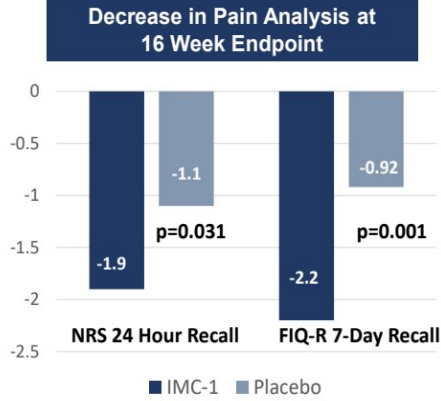
Purposeful Research Approach Focused on Herpes Virus Inhibition As A Novel Approach to FM Treatment



GI Biopsy Study Confirms Herpes Infection in Somatic Syndrome Disorders



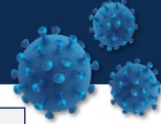
Phase 2a Clinical Study Identifies Potential of IMC-1



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



FORTRESS Phase 2b 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 Endpoint:
Reduction in Pain

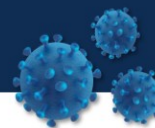
Key Secondary Endpoints:
PGIC, FIQ-R Domains,
30% & 50% pain responder analyses

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																

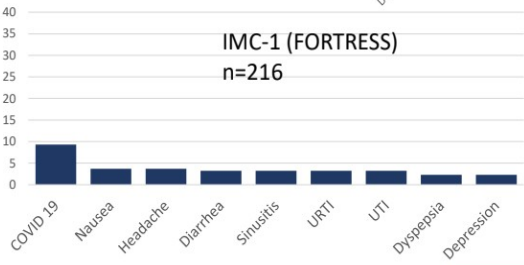
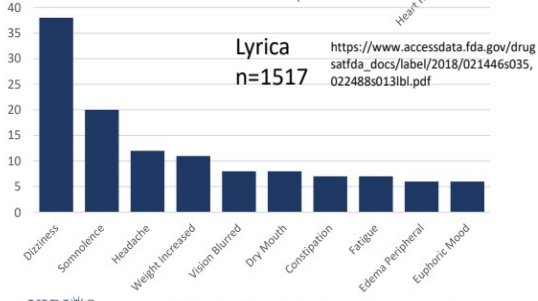
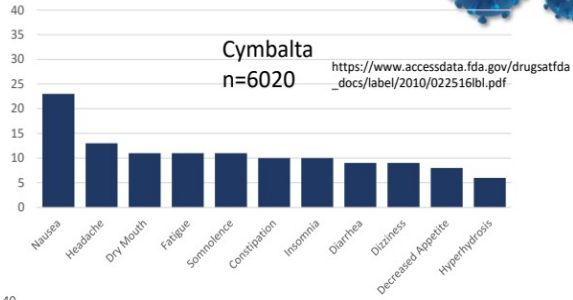
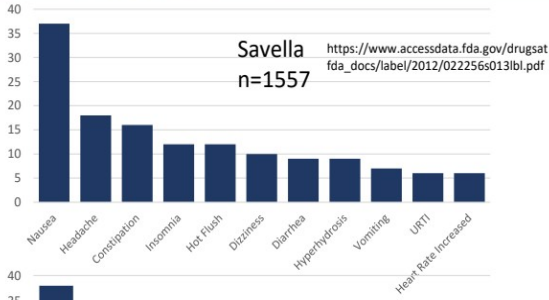
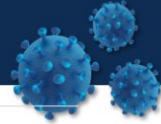
Prospectively Defined
Primary Endpoint Analysis

FORTRESS FM Phase 2b Study Disposition



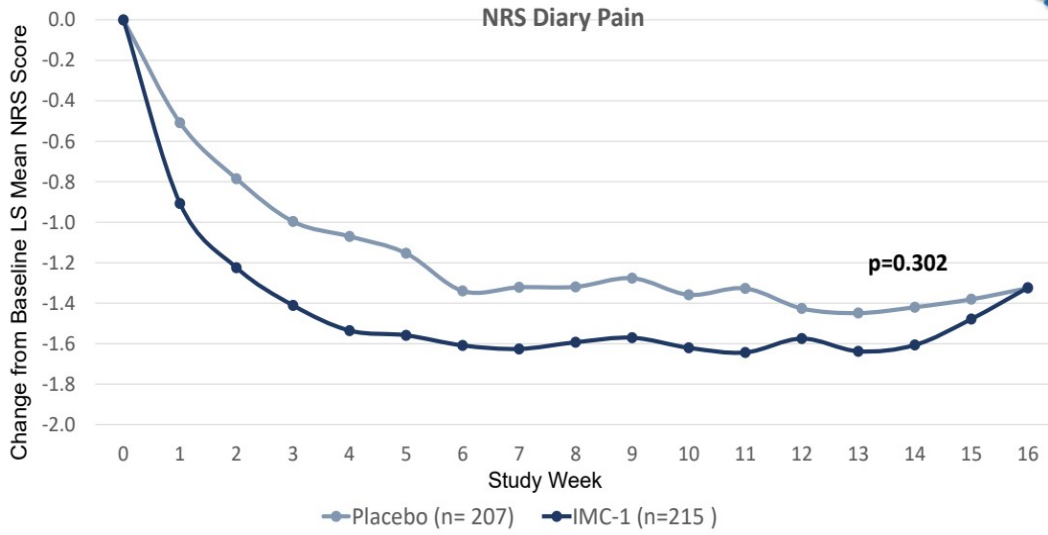
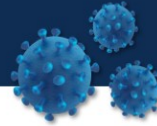
	Placebo	IMC-1	Total
	(N=209)	(N=216)	(N=425)
Randomized	209 (100.0%)	216 (100.0%)	425 (100.0%)
Completed	161 (77.0%)	176 (81.5%)	337 (79.3%)
Discontinued Early	48 (23.0%)	40 (18.5%)	88 (20.7%)
Discontinuation due to Adverse Events	17 (8.1%)	10 (4.6%)	27 (6.4%)

FM Treatment Tolerability: TEAEs > 5% from PIs*

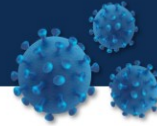


*Not a head to head comparison

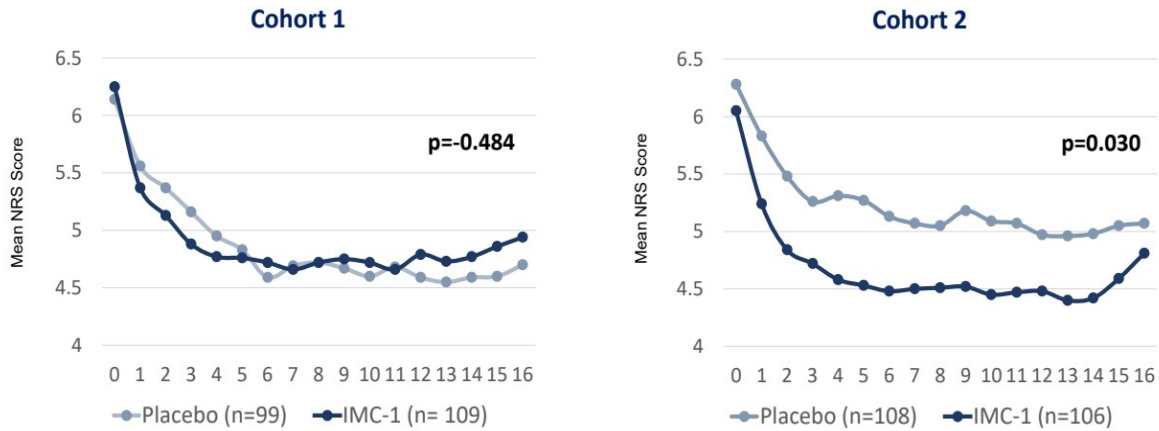
FORTRESS Primary Pain Reduction Result



IMC-1 Treatment Effect Similar in Both Cohorts, Early Enrollee Placebo Effect at Levels Previously Unseen

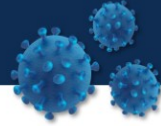


Decrease in NRS Pain at Week 14 Endpoint by Cohort



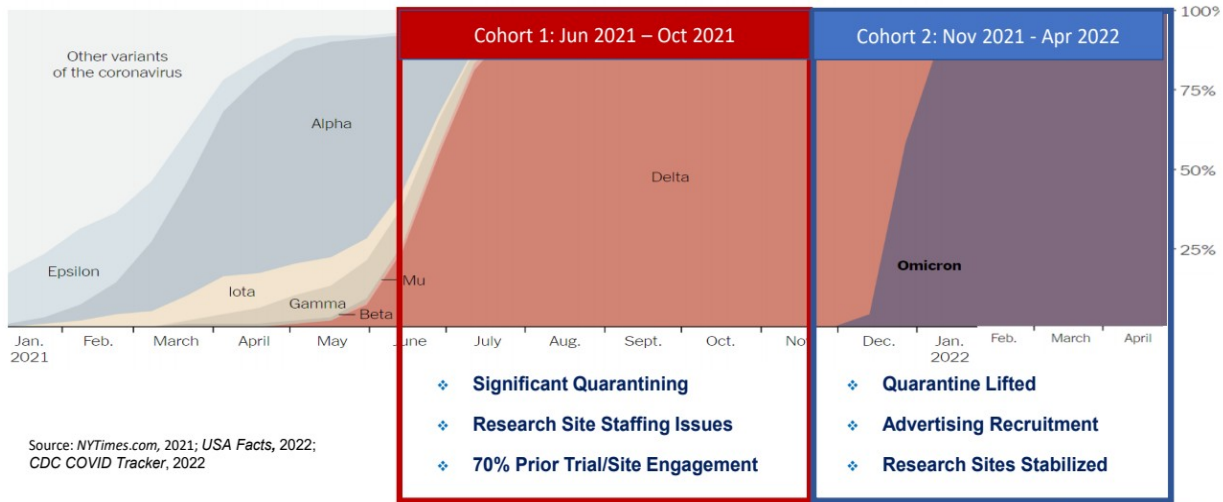
Three recent pain trials, including two FM trials, observed differing first half/second half treatment effects during Covid

Original Assessment of Enrollment Timing and COVID-19 Variants Potentially Impacting Placebo Response



Waves of Variants in the United States

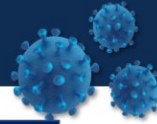
Omicron has pushed aside Delta as the dominant variant in the United States.



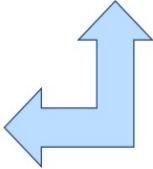
- ❖ Significant Quarantining
- ❖ Research Site Staffing Issues
- ❖ 70% Prior Trial/Site Engagement

- ❖ Quarantine Lifted
- ❖ Advertising Recruitment
- ❖ Research Sites Stabilized

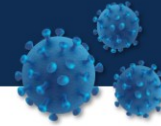
Factors Explored During Data Analysis



- ❖ Cohort 1 v Cohort 2 - Study entry date
- ❖ Recruitment by advertising – not previously involved in prior site trials
- ❖ Lifetime usage of FM treatment drugs (including washout)
- ❖ Recruitment at purely clinical research sites vs “mixed” (practice & research) sites
- ❖ Treatment-naïve patients
- ❖ Recruitment of patients from previous FM clinical trials
- ❖ Baseline pain variance
- ❖ Duration of fibromyalgia diagnosis
- ❖ Recruitment at psychiatric specialty sites
- ❖ Site readiness, personnel turnover



Advertising-Recruited Patients (“New”) Compared To Patients From Prior Trials, Databases and Clinical Practice (“Existing”)

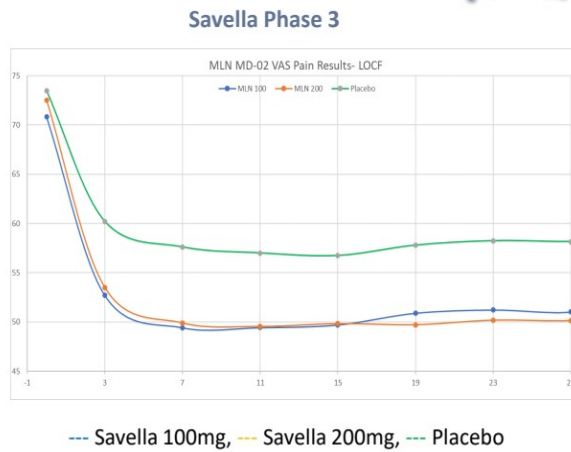
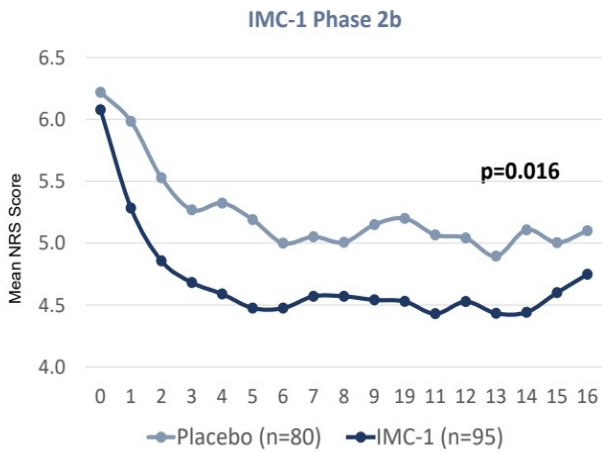
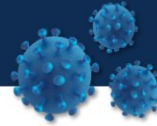


New vs Existing Patients	N	Placebo Change from Baseline @ Week 14	IMC-1 Change from Baseline @ Week 14	Contrast @ Week 14	P Value
Existing	247	-1.843	-1.594	+0.249	***
Advertising/ New	175	-1.024	-1.689	-0.665	0.016

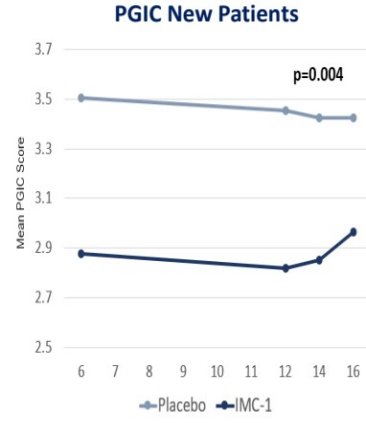
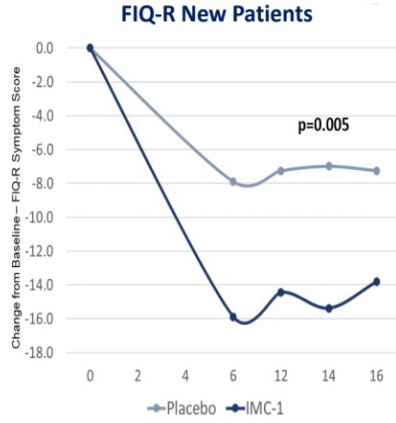
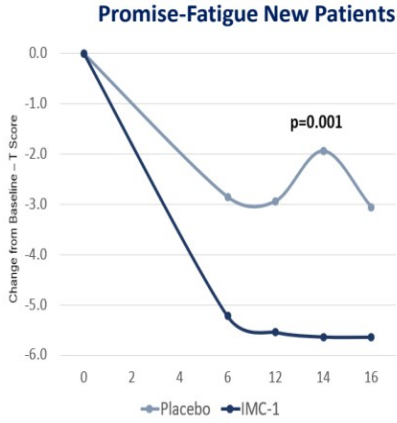
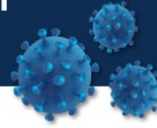
Advertising patients presumed to bring in patients who were largely new to clinical research, new to the site, and more likely to be FM Treatment-Naïve

Design Expectations:
 Placebo ~ -1.1 to -1.2
 IMC-1 ~ -1.7 to -1.8

“New” Patient Cohort Treated with IMC-1 Demonstrates Pain Reduction Consistent with Savella Phase 3 Patients

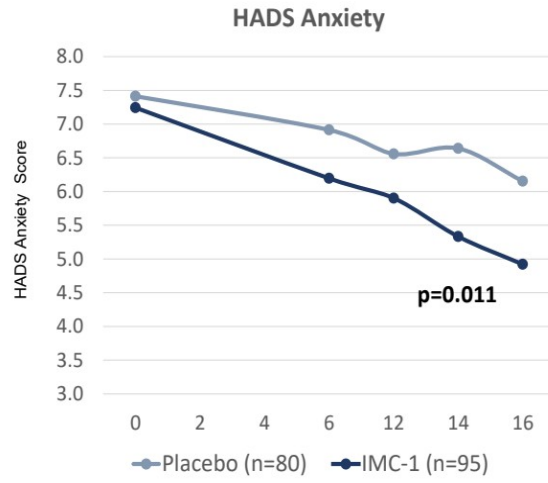
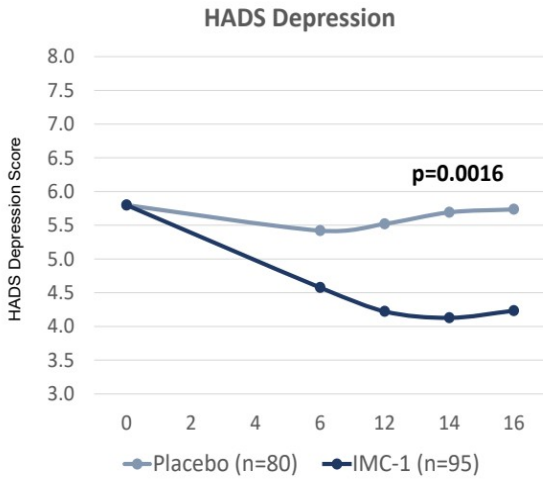
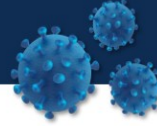


New FM Patients Demonstrate IMC-1 Treatment Effect on Key Secondary Outcomes - Entire Study Interval

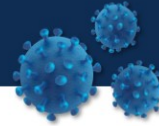


Overall n=175: Placebo n=80, IMC-1 n=95

New FM Patients Demonstrate Improved Mood-Related Endpoints - Entire Study Interval



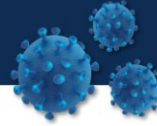
Site Recruitment: Research-Only Sites Compared to Mixed Research/Practice - Entire Study Interval



Research Site Or Not	n	Placebo Change from Baseline @ Week 14	IMC-1 Change from Baseline @ Week 14	Contrast @ Week 14	P Value
Research Sites	198	-1.445	-1.885	-0.439	0.050
Mixed Sites	224	-1.672	-1.528	+0.145	***

Design Expectations:
Placebo ~ -1.1 to -1.2
IMC-1 ~ -1.7 to -1.8

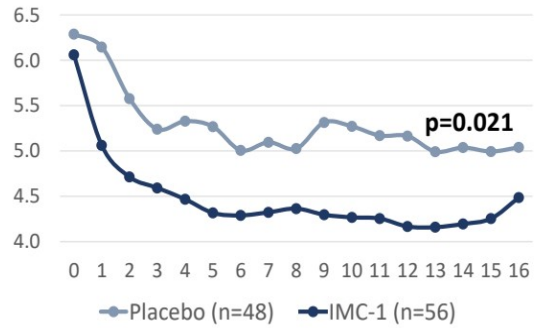
Result Order of Importance, Optimal Patient Response Observed in 104 Total Patients

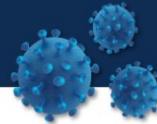


Defining the Optimal Patient:

- ❖ Recruited at tail end of pandemic (after November 2021)
 - ❖ Simulate no pandemic effects
- ❖ Recruited through social media advertising (more naïve patients)
 - ❖ Bias towards more naïve patients to avoid potentially refractory patients

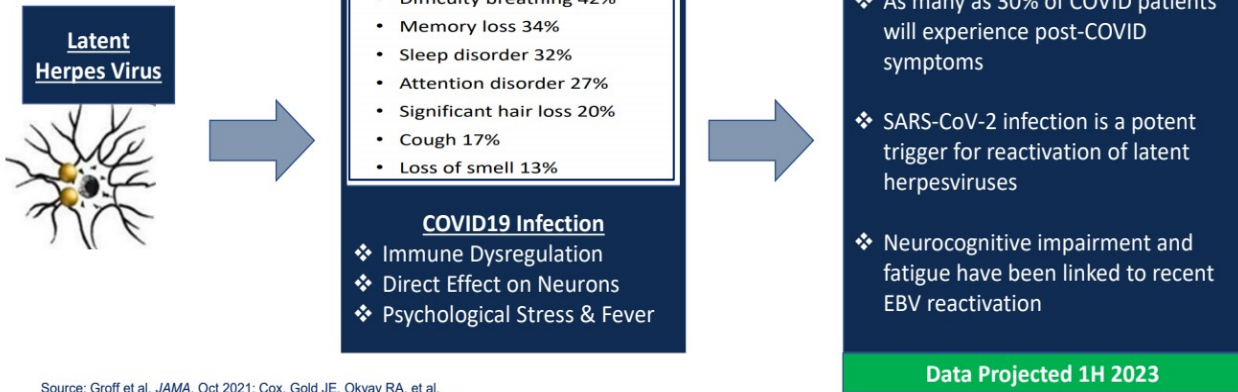
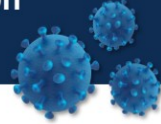
Optimal Target Patients
n=104





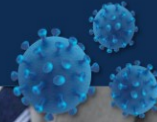
- ❖ Mechanistic link between herpes virus activation and FM
- ❖ Positive Phase 2a clinical study results
- ❖ Phase 2b Trial Results: FM patients who were new to the research sites demonstrated clinically and statistically significant reductions in:
 - Pain, fatigue, FM symptoms and both anxiety and depression symptoms
- ❖ IMC-1 consistently 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 in FORTRESS
- ❖ Company believes FORTRESS data supports progression to Phase 3 development

Potential Link Between Long-COVID and Herpes Virus Reactivation Drives Valacyclovir/Celecoxib Exploratory Trial



Source: Groff et al, JAMA, Oct 2021; Cox, Gold JE, Okyay RA, et al, Pathogens, 2022; E. Apostolou et al, Frontiers in Immunology, 2022; Traylen, Christopher Met al, Future virology, 2011; Bo Diao, Chenhui Wang, et al., 2019

Strong IP Portfolio with 21 Issued Patents to 2033



Four Issued US IMC-1 Patents

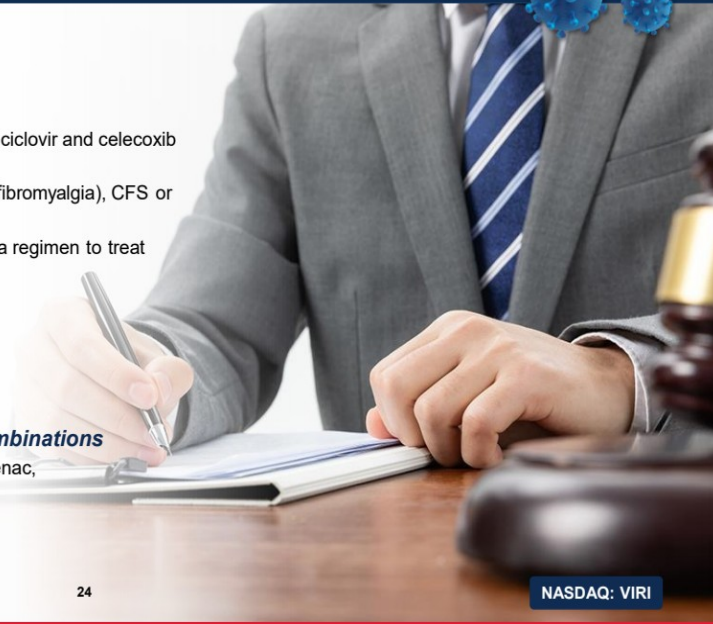
- **Two “Composition of Matter” Patents**
 - Drug-combination of famciclovir and celecoxib
 - Synergistic combination for total daily dose of famciclovir and celecoxib
- **Two “Method-of-Use” Patents**
 - Famciclovir + celecoxib for the treatment of FM (fibromyalgia), CFS or IBS
 - Method of dispensing famciclovir + celecoxib in a regimen to treat Functional Somatic Syndrome conditions

Six Issued Foreign IMC-1 Patents

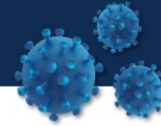
- European Patent validated in 18 countries
- Japan, Australia, China, South Korea and Canada

Eight US Patents Covering Other Anti-Viral Combinations

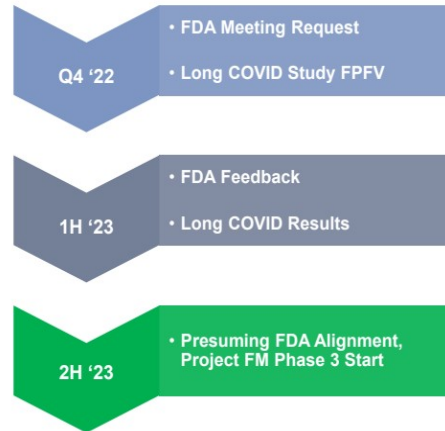
- Various combinations of acyclovir, meloxicam, diclofenac, famciclovir, valacyclovir, celecoxib



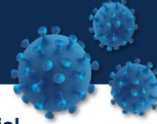
Combination Antiviral Research Pipeline Provides Rich Milestone Progression



Pipeline Candidates	Disease	Pre-Clinical	Phase 1	Phase 2	Phase 3
			Exploratory		
IMC-1: (famciclovir + celecoxib)	FM			Phase 2b	
IMC-1: (famciclovir + celecoxib)	IBS				
IMC-2: (valacyclovir + celecoxib)	Long COVID*		Exploratory		



* The CDC/National Center for Health Statistics estimates that one in five COVID-19 survivors aged 18–64 years and one in four survivors aged ≥65 years experiencing an incident condition that might be attributable to previous COVID-19, June 2022



❖ **First-in-Class Combination Antiviral Development Candidates Target Two Significant Commercial Opportunities:**

- Fibromyalgia (FM) impacts 2%+ of the population, novelty of approach garners FDA "Fast Track" review designation
- Long-Covid sequelae impacts @30% of Covid infected patients, exploratory trial top line data 1H 2023

❖ **Lead Candidate, Oral IMC-1 (famciclovir + celecoxib) Demonstrated Significant FM Treatment Benefits In Phase 2a Clinical Study:**

- Reduction in FM related pain, fatigue, anxiety, depression and sleep disruption, tolerability better than placebo

❖ **FORTRESS Phase 2b FM Data Demonstrates IMC-1's Exceptional Tolerability, Mixed Efficacy Results**

- New, research naive patients exhibit significant treatment effects
- Previously treated patients (e.g. prior research studies, prior treatment) fail to exhibit significant treatment effects
- Suggests we may be seeing "refractory" FM patients entering current clinical trials

❖ **Will approach FDA to discuss forward development plan: Feedback in 1H 2023**



THANK YOU!

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www.virios.com

