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): **March 1, 2022**

VIRIOS THERAPEUTICS, INC.
(Exact Name of Registrant as Specified in Charter)

Delaware	**001-39811**	**45-4618270**
(State or other jurisdiction of incorporation)	(Commission File Number)	(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 March 1, 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 Private Securities Litigation Reform Act of 1995. 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" 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: the outbreak of the novel coronavirus disease, 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 candidate; 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, 2020 filed with the Securities and Exchange Commission ("SEC") and elsewhere in our filings and reports with the SEC. These risks, uncertainties and other factors may cause our actual results to differ materially and adversely from what is contained in (or may be implied from) any forward-looking statements. Forward-looking statements speak as of the date they are made, and the Company undertakes no obligation to update them except as may be required under applicable law.

Item 9.01 Financial Statements and Exhibits.

(d)_____Exhibits.

Exhibit Number	Description
99.1	Presentation dated March 2022 (furnished herewith).
104	Cover Page Interactive Data File (formatted in Inline XBRL and contained in Exhibit 101)

SIGNATURES

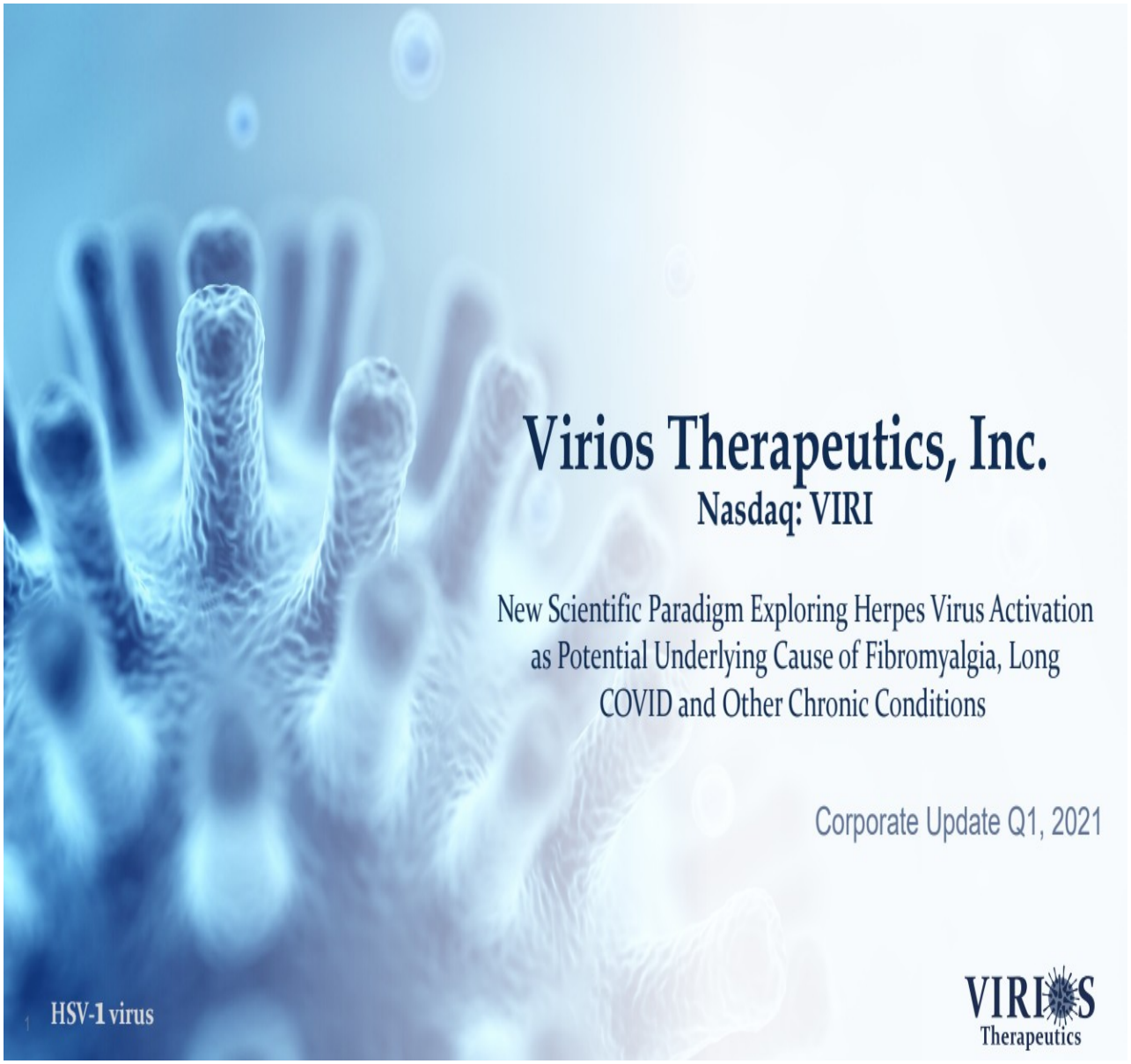
Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

VIRIOS THERAPEUTICS, INC.

By: /s/ Angela Walsh
Name: Angela Walsh
Title: SVP of Finance and Corporate Secretary

March 1, 2022

Exhibit 99.1


Virios Therapeutics, Inc.
Nasdaq: VIRI
New Scientific Paradigm Exploring Herpes Virus Activation as Potential Underlying Cause of Fibromyalgia, Long COVID and Other Chronic Conditions
Corporate Update Q1, 2021
HSV-1 virus
VIRIOS 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 outbreak of the novel coronavirus disease, 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, 2020 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.

Virios Therapeutics Summary

Focused on Two Significant Commercial Opportunities:

- The Large, Dissatisfied **Fibromyalgia** (FM) Market: 2%-8% of the Population
- **Long COVID**, a Rapidly Emerging Unmet Need: Impacts an Estimated 100M Post-COVID Patients Worldwide

Oral IMC-1 (famciclovir + celecoxib) Demonstrated Significant Pain Reduction Benefits and Tolerability Better Than Placebo in P2a FM Trial:

- Ongoing Phase 2b FM Trial Results in Q3 2022
- Composition Of Matter IP to 2033
- First Ever FDA "Fast Track" Review Designation for FM Treatment

Oral IMC-2 (valacyclovir + celecoxib) in Ongoing Phase 2a Long COVID Treatment Trial:

- COVID-19 acutely depletes our T cells, which may allow for reactivation of Herpes viruses
- Immune dysregulation may re-activate neurotrophic pathogens such as herpes viruses

Virios Team and Board of Directors Have Led Development and Commercialization of Many Category Leading Medicines:

- Includes Two of Three FDA Approved FM Medicines

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
VP of Operations

Pharma Brand Development & Commercialization Experience Includes Management of:

Zoloft (sertraline HCl)
Lipitor (atorvastatin calcium)
Aricept
Zyrtec
Viagra (sildenafil citrate)
Celebrex
Lyrica (pregabalin)
Savella (milnacipran HCl)

DIRECTORS

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

Abel De La Rosa, PhD
- Chairman, Co-Founder Antios Therapeutics
- Led Bus Dev for Pharmasset acquisition by GILD for $11.5 billion in 2012
- Provided Leadership for Development Programs for the Treatment of HIV, Hepatitis B & C, including Sofosbuvir

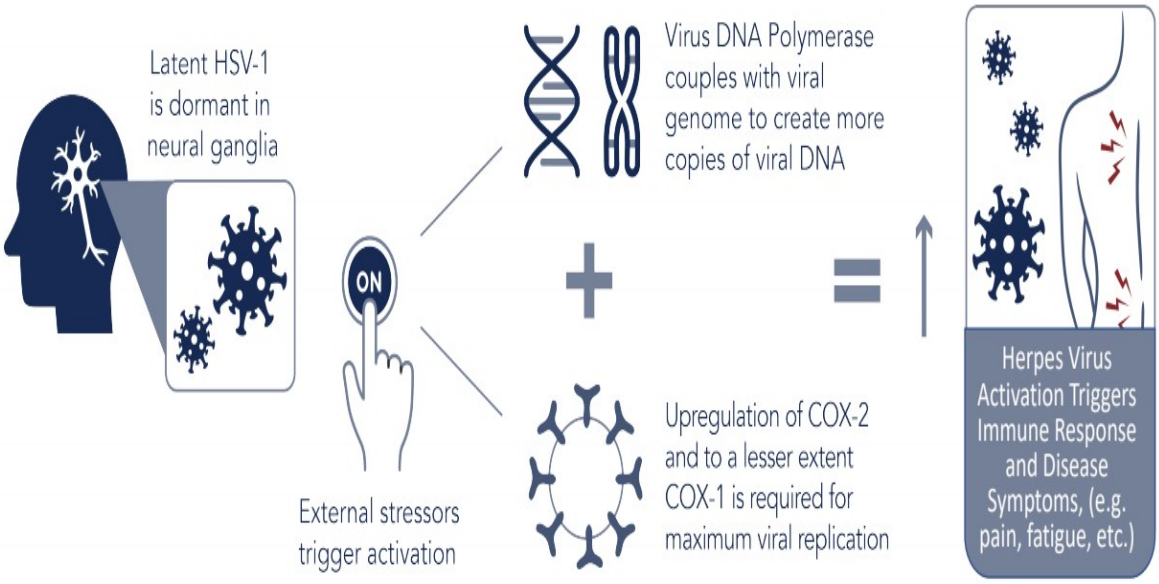
John Thomas, CPA
- CorMatrix, Inc., MiMedx Group, Inc.
- DARA BioSciences, GMP Companies,
- MRI Interventions, EnterMed, Inc.,
- Medicis Pharm Corp., CytRx Corp

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

Rick Burch
- 30 years at PFE including Senior Vice President overseeing numerous divisions with more than 6,500 employees
- VP and GM UCB Pharmaceuticals
- President of Virios Therapeutics, Inc.

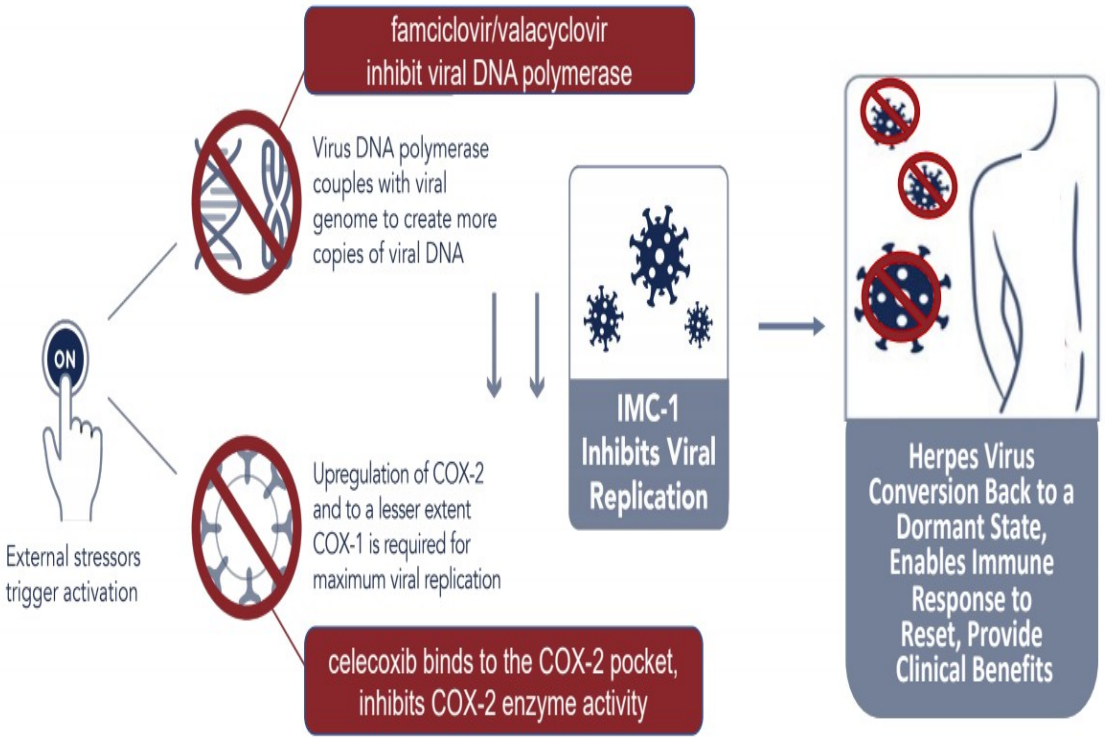
Skip Pridgen, MD
Founder
- Company Founder
- Board- certified surgeon practicing with Tuscaloosa Surgical Associates, P.C.
- Served as a physician and surgeon US Navy

Discovery Implicates Dormant Herpes Virus Reactivation Triggers Immune Response, Manifestation of FM and Long COVID



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 Ibañez et al, *Frontiers in Microbiology*, 2018,

Synergistic Antiviral Mechanism Serves as the Basis for Proposed Fibromyalgia and Long COVID Treatment Effect



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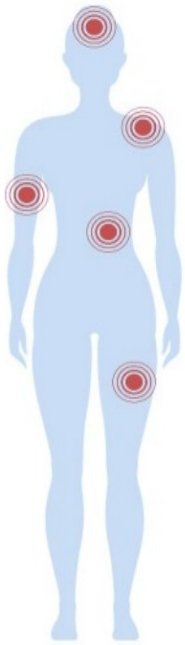
Fibromyalgia Disease Overview

Disease Characteristics

- FM is a Chronic Disease that Affects up to 8% of the US Population
- Hallmark Characteristics are Widespread Chronic Pain and Severe Fatigue
  - Symptoms Present for ≥ 3 Months
- Other Symptoms May Include GI, Sleep, Mood Disorder and Headache



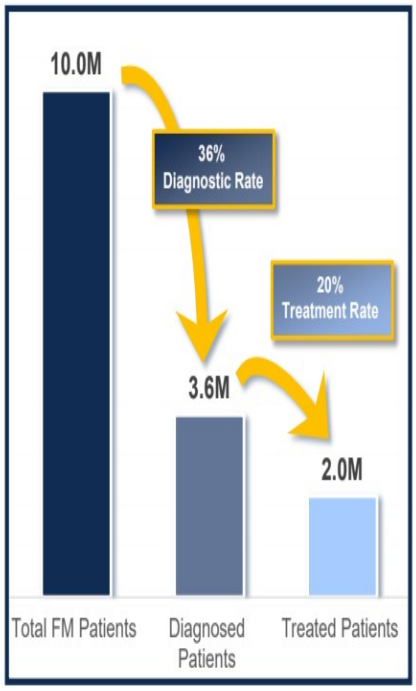
Devastating Impact

- Patients with FM > 3x Risk of Committing Suicide v. General Population
- High Healthcare Utilization and Significant Disability
- Estimates Suggest as Many as 40% of FM Patients are Treated with Opioids
  - Opioid-treated Patients have Worse Outcomes Across Multiple Assessment Domains

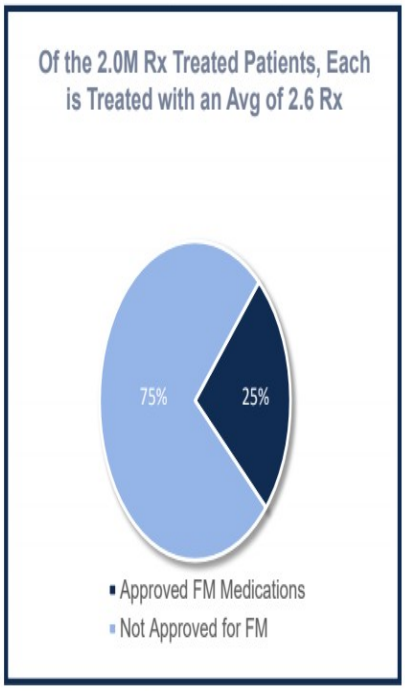
Sources: The Hidden Impact of Musculoskeletal Disorders on Americans, 4th edition; Berger et al *Clin Pract* 2007; White et al *J Occup Environ Med* 2008; Wolfe et al *Arthritis Care & Res* 2014; Fitzcharles et al *Am J Med* 2011; Robinson et al *Pain Medicine* 2012; Peng et al *Clin J Pain* 2015

The Fibromyalgia Market is Large and Poised for Growth *IF* Better Therapeutic Options Emerge

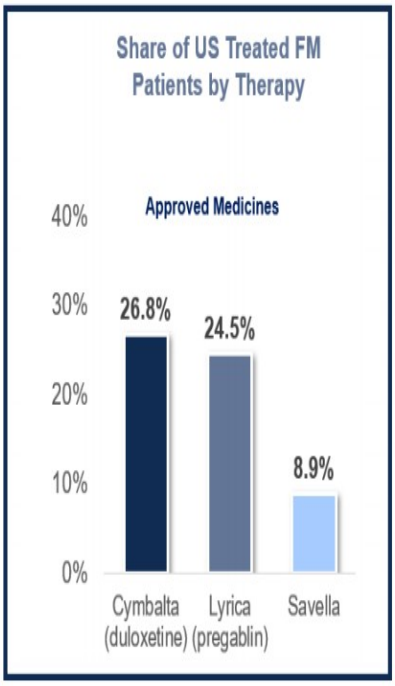
Significant Growth Potential Still Exists



Most US Treated Patients on Multiple Therapies



Global FM Market Sales Estimated at $1.9B in 2019



Source: National Fibromyalgia and Chronic Pain Association 2021; Vincent, A et al *Arthritis Care Research* 2013; Robinson et al *Pain Medicine*, 2012, *Fortune Business Insights*, 2021

IMC-1: Completed Phase 2a Clinical Proof of Concept Trial

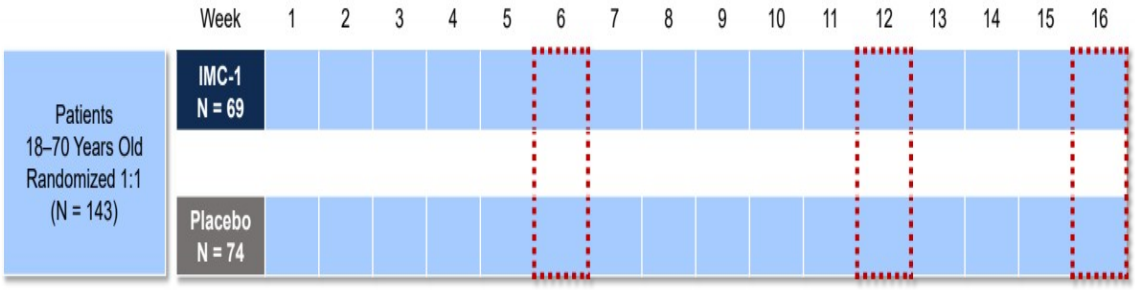
Design Summary:

- Randomized, Double-blind, Multi-center, Placebo-controlled
- IMC-1 (famciclovir + celecoxib) vs Placebo, Dosed Twice Daily
- Diagnosis of Fibromyalgia Using 2010 American College of Rheumatology

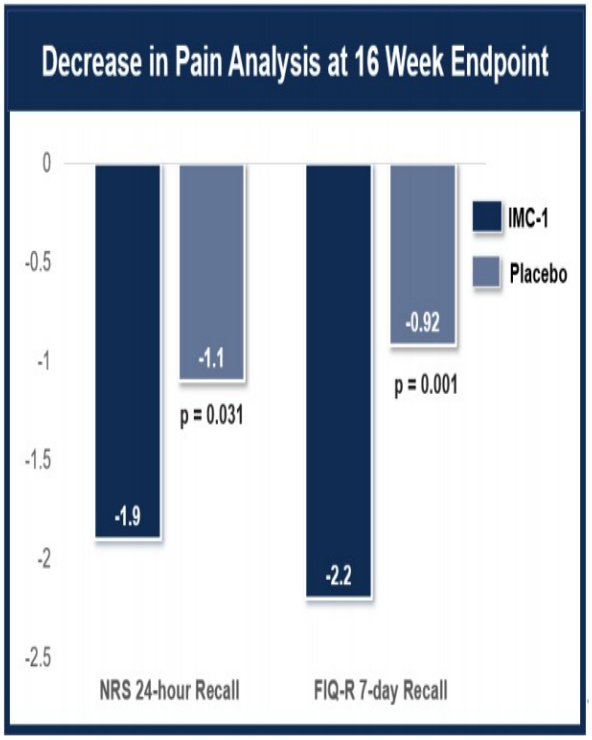
Primary Endpoints
Reduction in Pain

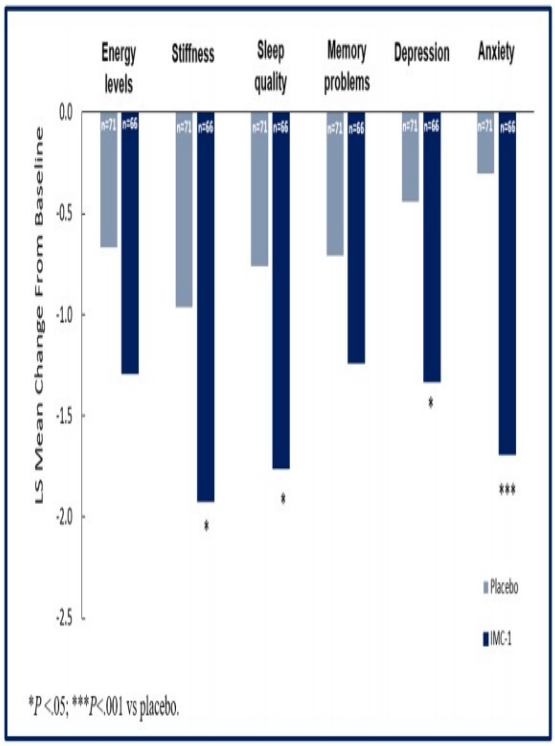
Key Secondary Endpoints
PGIC, FIQ-R Domains, 30% & 50% pain responder analyses

Received study drug treatment for a total of 16 weeks



IMC-1 Demonstrated Statistically Significant Reduction in Pain in Phase 2a Clinical Trial





Source: Pridgen et al, *Journal of Pain Research*, 2017, Virios Therapeutics, Inc.

IMC-1 Treatment Resulted in Consistent Treatment Effects and Tolerability Better Than Placebo at 16 Weeks

Secondary Endpoints	P Value
PROMIS (NIH) Fatigue Assessment	p=0.001
PGIC - Patient's Global Impression of Change	P=0.040
FIQ-R - Revised Fibromyalgia Impact Questionnaire Total Score	p=0.002
FIQ-R – Functional Domain	p=0.004
FIQ-R – Overall Impact Domain	p=0.003
FIQ-R – Symptoms Domain	p=0.004
Pain Responder Analysis – **50% Pain Reduction** • 24 Hour Recall NRS • 7 Day Recall NRS	 p=0.009 p=0.001
Pain Responder Analysis – **30% Pain Reduction** 24 Hour Recall NRS @ week 16 7 Day Recall NRS @ week 16	 p=0.052 p=0.012
Use of Rescue Medication	p=0.037

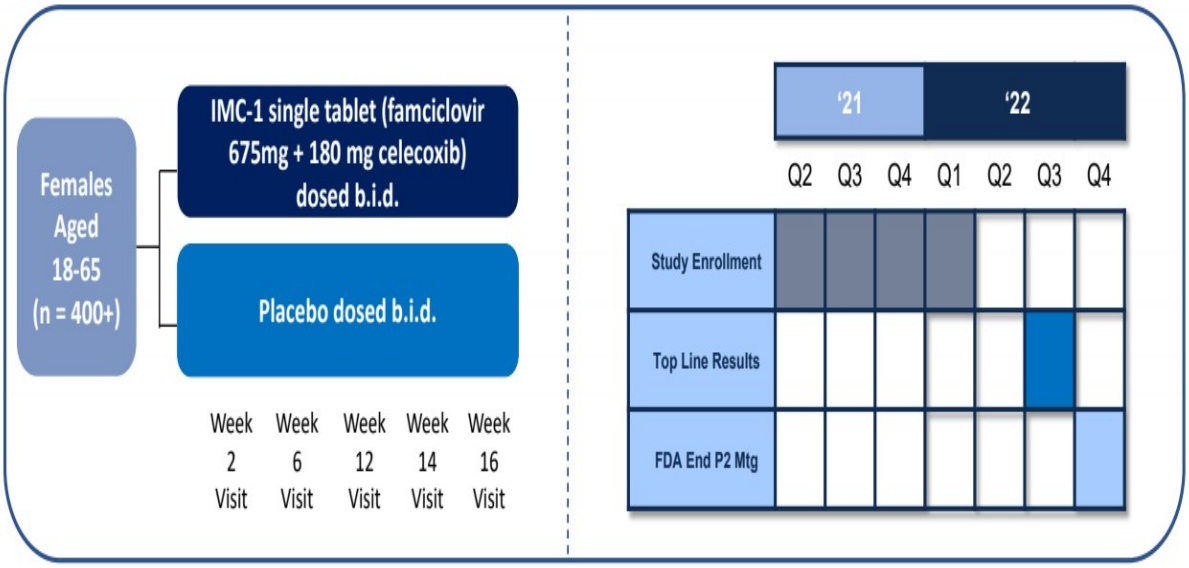
Phase 2a Trial	Placebo	IMC-1	IMC-1 Difference
Discontinuation reasons:			
Adverse event (p=0.012)	12 (16.2%)	4 (5.8%)	2.8X reduction
Therapeutic failure	12 (16.2%)	5 (7.2%)	2.3X reduction
Other	5 (6.8%)	3 (4.4%)	1.5X reduction

Source: Pridgen et al, *Journal of Pain Research*, 2017, Virios Therapeutics, Inc.

IMC-1 Phase 2b Design Conducted Using Optimized IMC-1 Dosage, 350+ Patients Presently Enrolled

Primary Endpoint
Reduction in pain measured daily

Key Secondary Endpoints
Fatigue, sleep, PGIC, FIQ-R domains, 30% & 50% pain responder analyses



Long COVID Prevalence is Significant and Represents an Emerging Unmet Medical Need

- The mechanisms by which COVID-19 causes lingering symptoms in survivors are not fully understood but are hypothesized to result from:
  - Immune-system dysregulation triggered by the COVID-19 virus, including increased production of autoantibodies
  - Lingering infection
  - Co-infection/activation of previous viral infections that were dormant
- Most adults are infected with normally harmless dormant viruses, contracted years earlier
- COVID-19 acutely depletes our T cells, which may allow for reactivation of herpes viruses
- Antiviral therapy may hold promise for treating Long COVID
  - Valacyclovir, famciclovir and acyclovir inhibit replication of common Herpes viruses
  - Valacyclovir has been shown to reduce the frequency of EBV-infected (HHV-4) B cells

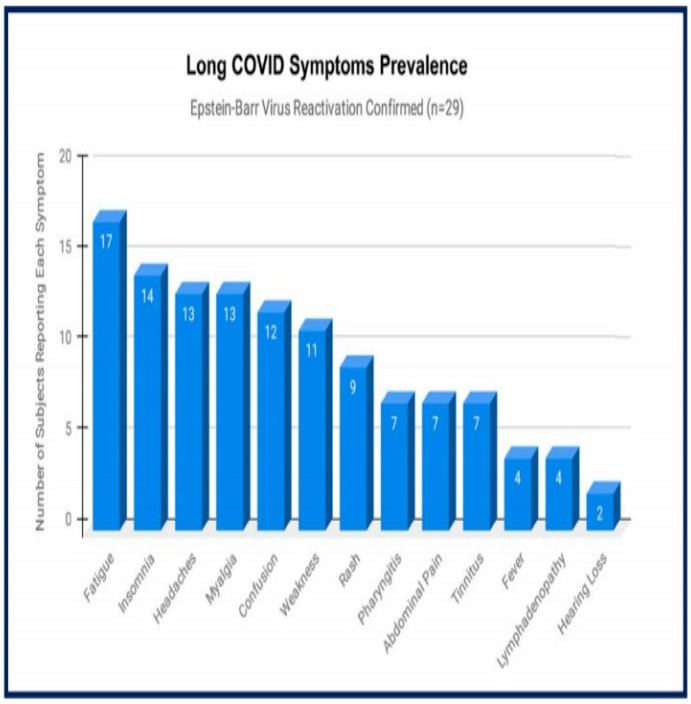
Sources: Groff et al, *JAMA*, Oct 2021; J Gold, *Pathogens*, 2021; Cox et al, *Research*, Penn State University, *Jan 22*

Common Symptoms Noted In Post-COVID Patients

Persistent Symptoms

- Fatigue 55%
- Difficulty breathing 42%
- Memory loss 34%
- Sleep disorder 32%
- Attention disorder 27%
- Significant hair loss 20%
- Cough 17%
- Loss of smell 13%

120 patients (mean = 111 days)

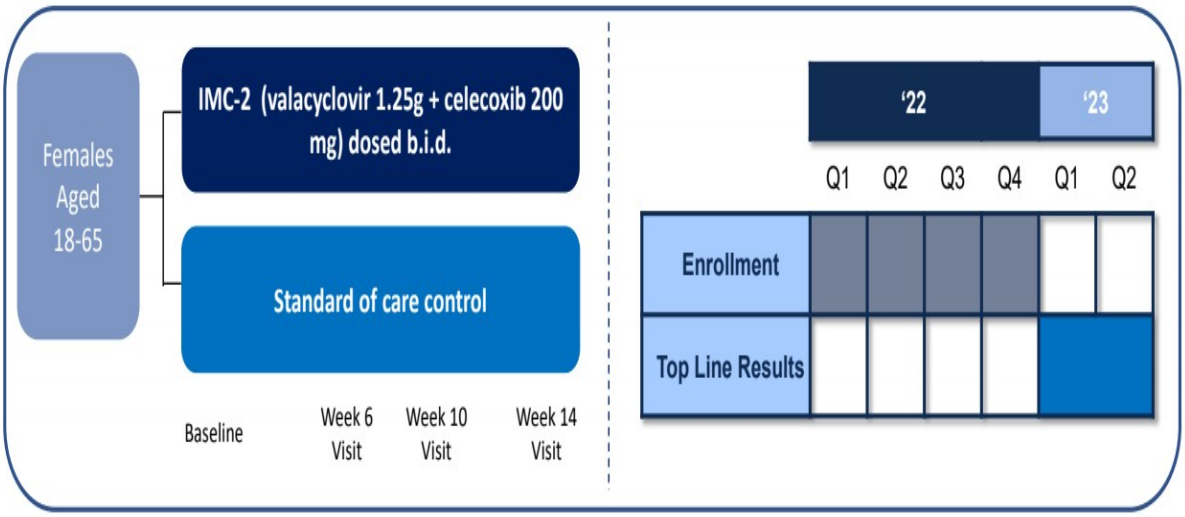


❖ Fatigue is Consistently the Most Common Symptom Amongst Long COVID Patients

Source: Garrigues et al. *Infect.* 2020; Carifi, et. al. *JAMA.* 2020; J Gold, *Pathogens*, 2021; F Bai, *Clinical Microbial Infections, 2021*

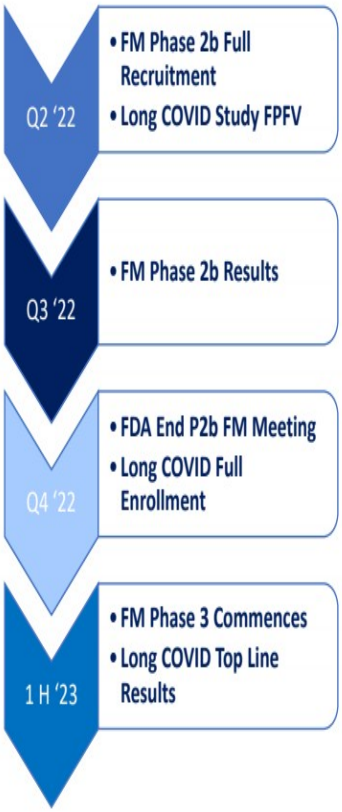
IMC-2 Exploratory Long COVID Study

Exploratory Endpoints Include : Fatigue, pain, sleep, anxiety, depression, cognitive function and global improvement



Combination Antiviral Research Pipeline Provides Rich Milestone Progression

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



Strong IP Portfolio with 21 Issued Patents

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, Korea and Canada

Eight US Patents Covering Other Anti-Viral Combinations

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

Capitalization Table as of December 31, 2021

VIRIS Therapeutics	
Exchange/Symbol	Nasdaq/VIRI
Common Shares Outstanding	8,330,390
Underwriters Warrants (Exercisable at $12.50/share)	172,500
Stock Options* (Employees, Directors & Officers)	1,041,647
Fully Diluted Shares Outstanding	9,544,537
Management Ownership** on a Fully Diluted Basis	20.2%
Cash on Hand	$14.0M

*Weighted Avg. Exercise Price of $9.03/share, **Includes officers and directors

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Virios Team and Board of Directors Have Led Development and Commercialization of Many Category Leading Medicines:

- Includes Two of Three FDA Approved FM Medicines


Thank You!
For Additional Information, Contact:
Kirin Smith: ksmith@pcgadvisory.com or ir@virios.com
20 HSV-1 virus
www.virios.com
VIRIOS
Therapeutics