

**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): **October 12, 2021**

VIRIOS THERAPEUTICS, INC.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or other jurisdiction
of incorporation)

001-39811
(Commission
File Number)

45-4618270
(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 October 12, 2021, 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 October 2021 (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

October 12, 2021

Virios Therapeutics, Inc.

(Nasdaq: "VIRI")

New Scientific Paradigm Exploring Herpes Simplex 1
(HSV-1) Virus Activation as Potential Underlying Cause
of Fibromyalgia and Other Chronic Conditions

Corporate Update Q4, 2021

HSV-1 virus

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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 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. 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 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



The Fibromyalgia (FM) Market is Large, but Dissatisfied – Highlighting Significant Commercial Potential for a Differentiated New FM Treatment



Novel Combination Antiviral Therapy, Oral IMC-1 (famciclovir + celecoxib), is Supported by Significant Pain Reduction Benefits in Phase 2a FM Trial

- IMC-1 Enjoys Composition Of Matter IP to 2033
- First Ever “FDA Fastrack Review” Designation for FM Treatment



Virios Team and Board of Directors Have Led Development or Commercialization for Two of Three FDA Approved FM Medicines



Proven Leadership Team with Experience in Fibromyalgia (FM) Development and Commercialization

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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:



Rich Whitely, MD

- Distinguished Professor, UAB
- Gilead Board of Director
- Remdesivir was Originally Developed by Dr Whitely'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., CylRx 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 Virocs 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

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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

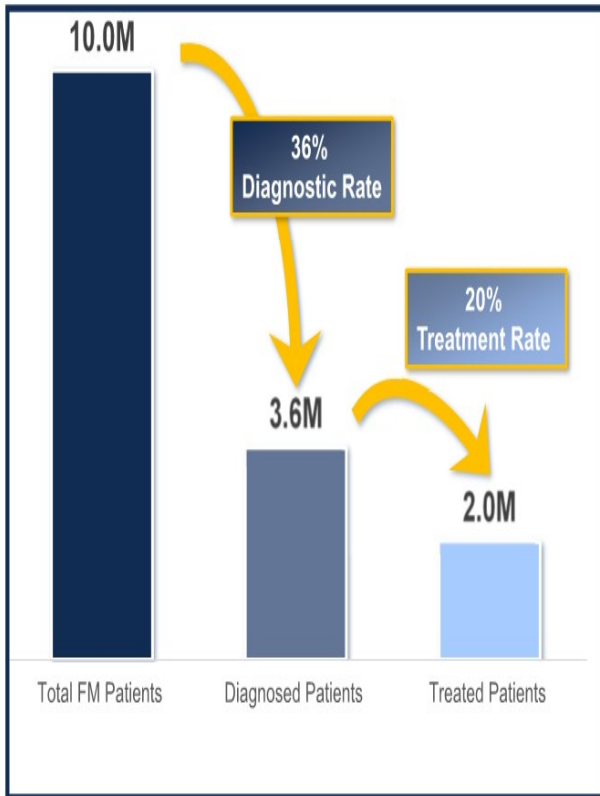
- Patients with FM > 3x Risk of Committing Suicide v. General Population
- High Healthcare Utilization and Significant Disability
- Estimates Suggest as Many as 40% of FM Patients are Treated with Opioids
 - Opioid-treated Patients have Worse Outcomes Across Multiple Assessment Domains



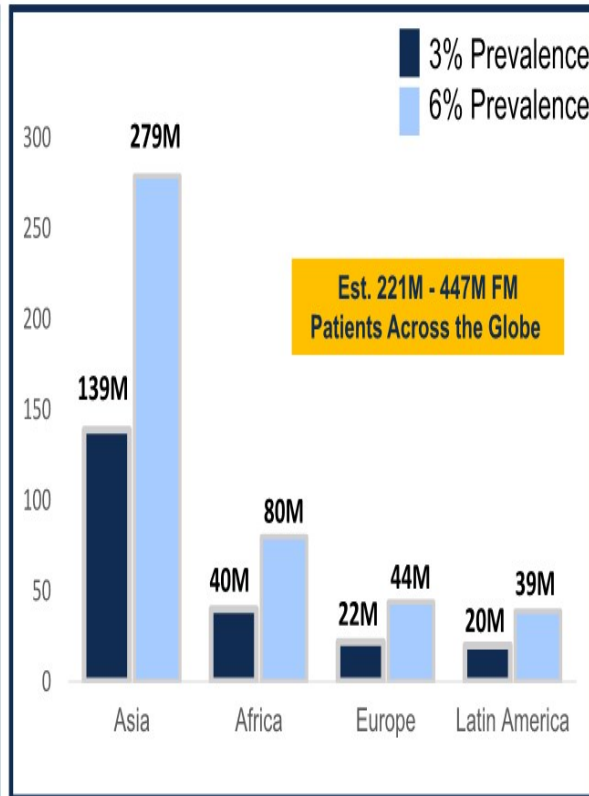
Sources: The Hidden Impact of Musculoskeletal Disorders on Americans, 4th edition; Berger et al *Clin Pract* 2007; White et al *J Occup Environ Med* 2008; Wolfe et al *Arthritis Care & Res* 2014; Fitzcharles et al *Am J Med* 2011; Robinson et al *Pain Medicine* 2012; Peng et al *Clin J Pain* 2015

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

Significant US FM Market
Growth Potential Still Exists



Worldwide FM Prevalence Ranges
From 3%-6% of the Population

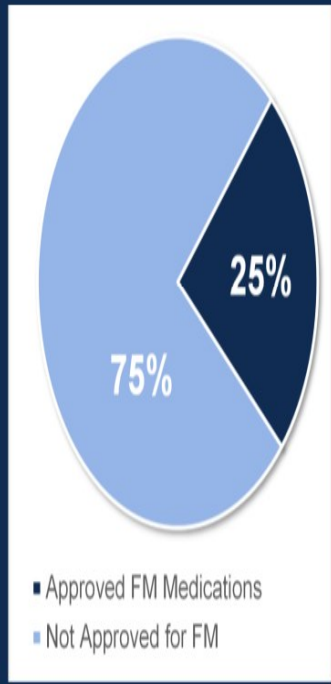


Source: National Fibromyalgia and Chronic Pain Association 2021; Vincent, A et al *Arthritis Care Research* 2013; Robinson et al *Pain Medicine*, 2012

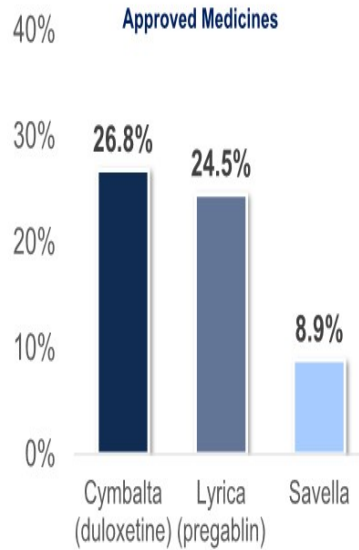


Polypharmacy and Utilization of Unapproved Therapies Demonstrate Significant Unmet Need

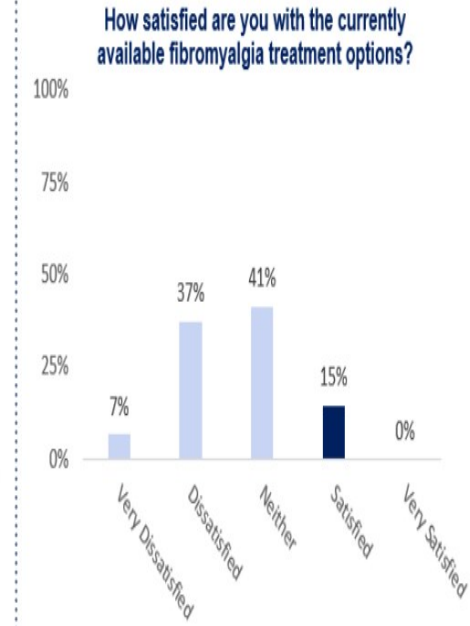
- 2.0M Rx Treated FM Patients
- Avg 2.6 Rx per Patient



Share of US Treated FM Patients by Therapy



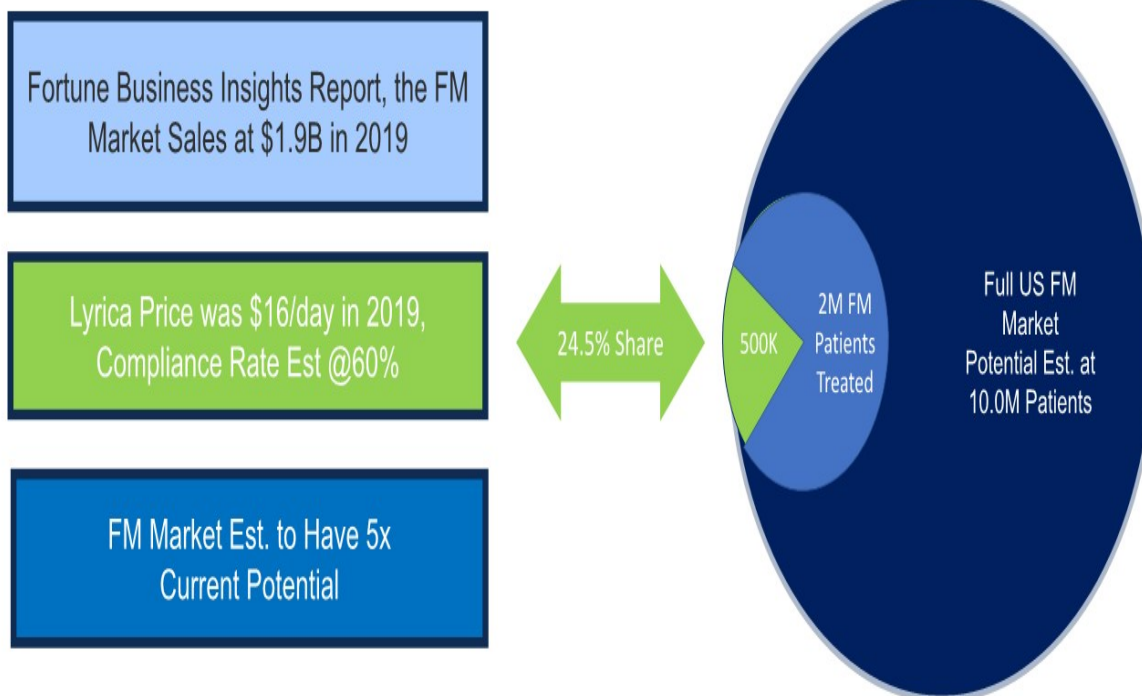
Only 15% of FM Treatment Prescribers Reported Satisfaction with Existing Treatments



7 Source: Robinson et al, *Pain Medicine*, 2012, . Lumleian primary research for Virios Therapeutics, Inc.

A New Treatment for Fibromyalgia Could Have Significant Commercial Potential in the US Market Alone

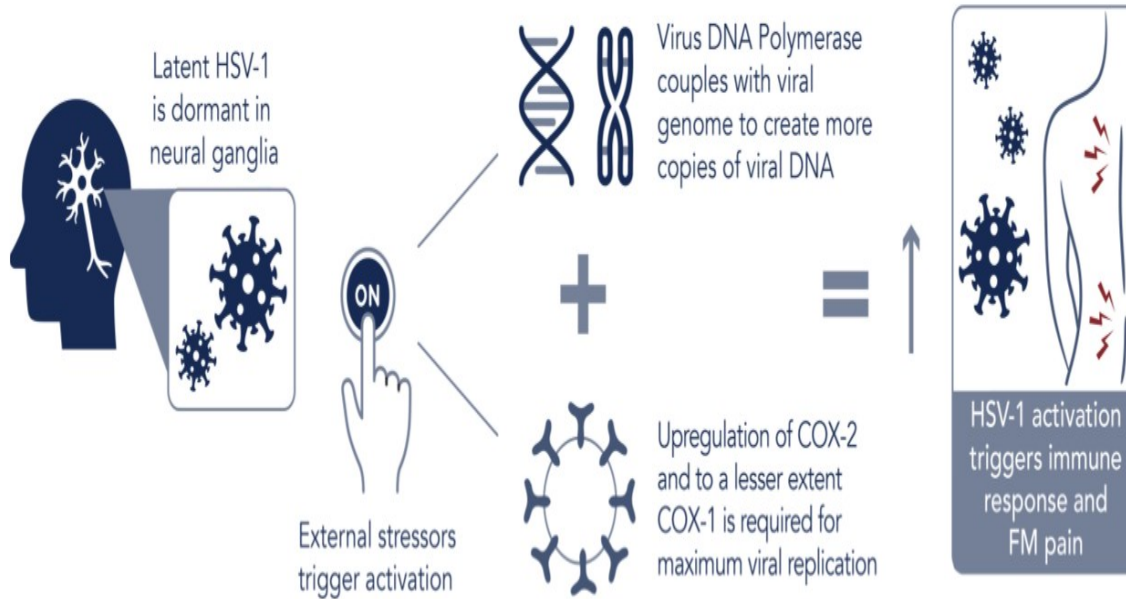
Total Projected US FM Community



8 Source: *Express Wire*, 2019, National Fibromyalgia and Chronic Pain Association, 2021; *Evaluate Pharma*, 2019; Robinson et al *Pain Medicine* 2012, Vincent et al *Arthritis Care Research*, 2013; *Redbook*, 2019



Discovery Implicates Dormant HSV-1 Reactivation Triggers Immune Response and Manifestation of Fibromyalgia

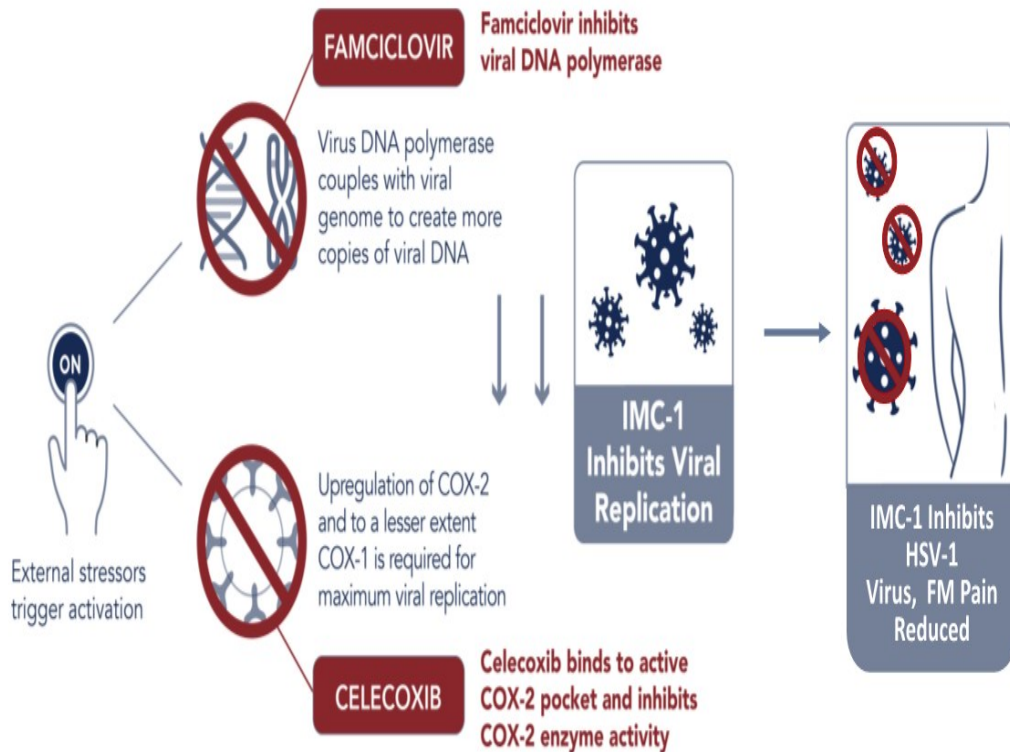


The World Health Organization Estimates That 3.7 Billion People Under the Age of 50 – or 67% of the Population are infected with Herpes Simplex Virus Type 1 (HSV-1), a Life-long Infection

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,

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IMC-1's Synergistic Antiviral Mechanism Serves as Basis for Proposed Fibromyalgia 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

IMC-1 Target Antiviral Mechanism Corroborated by GI Biopsy Research Executed with the University of Alabama

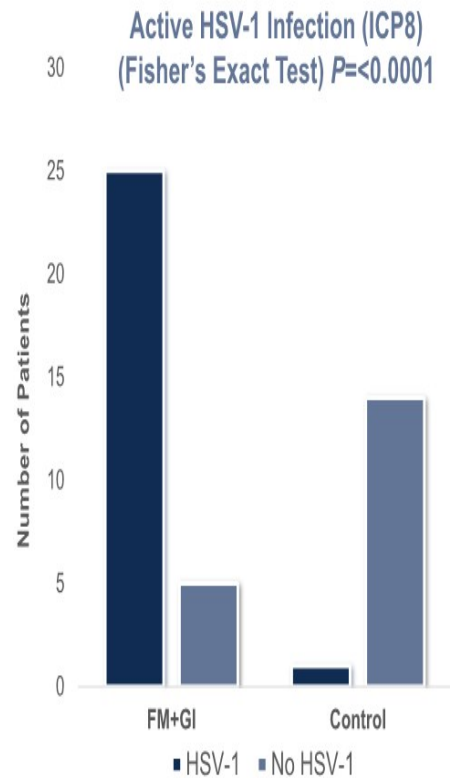
Viral GI Tissue Study:

Patient population:

- 30 Patients who Presented with Both FM and a Chronic GI Disorder
- 15 Control Patients, No FM or GI Disorder

GI Biopsies were Evaluated for Herpesvirus Infection:

- Analysis for ICP8 Viral Protein
- ICP8 Only Present During Active HSV-1 Infection
- PCR was Used to Detect Herpesvirus DNA



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

Design Summary:

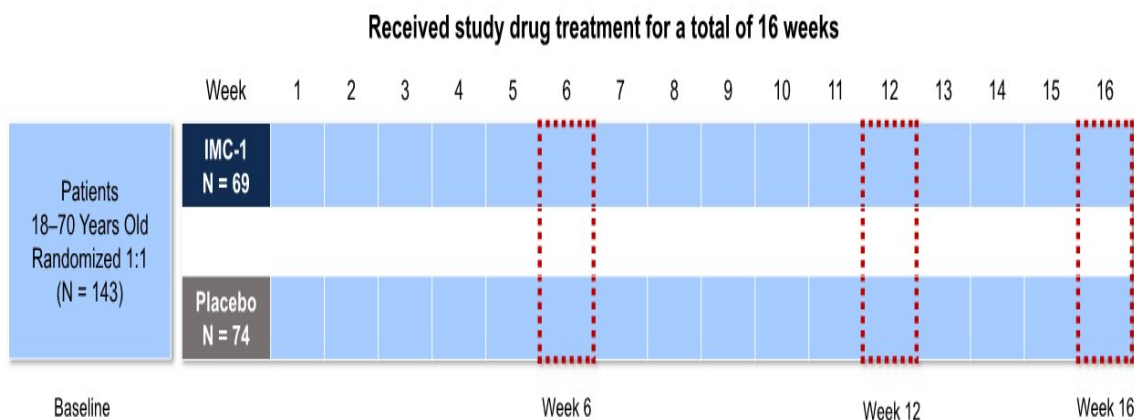
- Randomized, Double-blind, Multi-center, Placebo-controlled
- IMC-1 (famciclovir + celecoxib) vs Placebo, Dosed Twice Daily
- Diagnosis of Fibromyalgia Using 2010 American College of Rheumatology, Assessments at Weeks 6, 12 and 16

Primary Endpoints

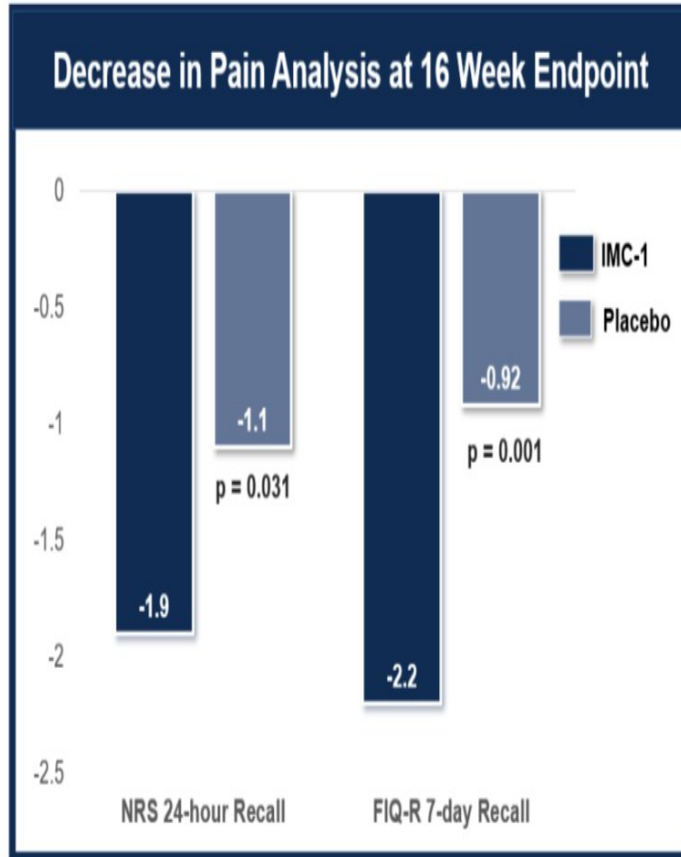
Reduction in Pain

Key Secondary Endpoints

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



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

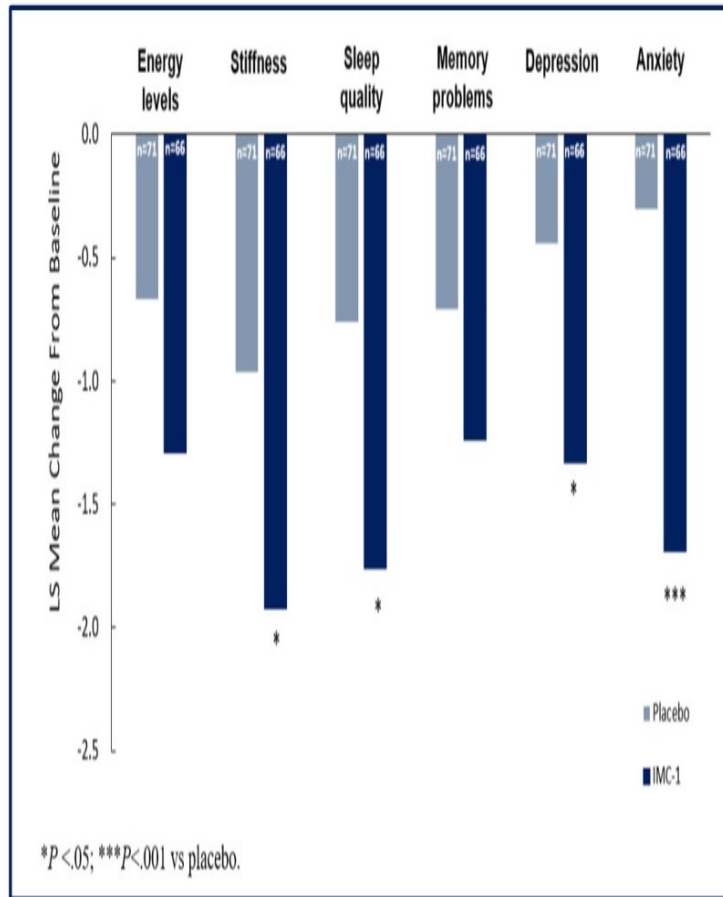


Source: Pridgen et al, *Journal of Pain Research*, 2017, Virios Therapeutics, Inc.

IMC-1 Treatment Resulted in Consistent Treatment Effects at 16 Weeks Across Spectrum of Fibromyalgia Endpoints

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	p=0.009
• 7 Day Recall NRS	p=0.001
Pain Responder Analysis – 30% Pain Reduction	
24 Hour Recall NRS @ week 16	p=0.052
7 Day Recall NRS @ week 16	p=0.012
Use of Rescue Medication	p=0.037

Key Secondary Outcomes at 16 Weeks



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

IMC-1 Had a Lower Discontinuation Rate Versus Placebo in Fibromyalgia Phase 2a Study

		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

IMC-1 Phase 2b Design to be Conducted Using Optimized IMC-1 Dosage

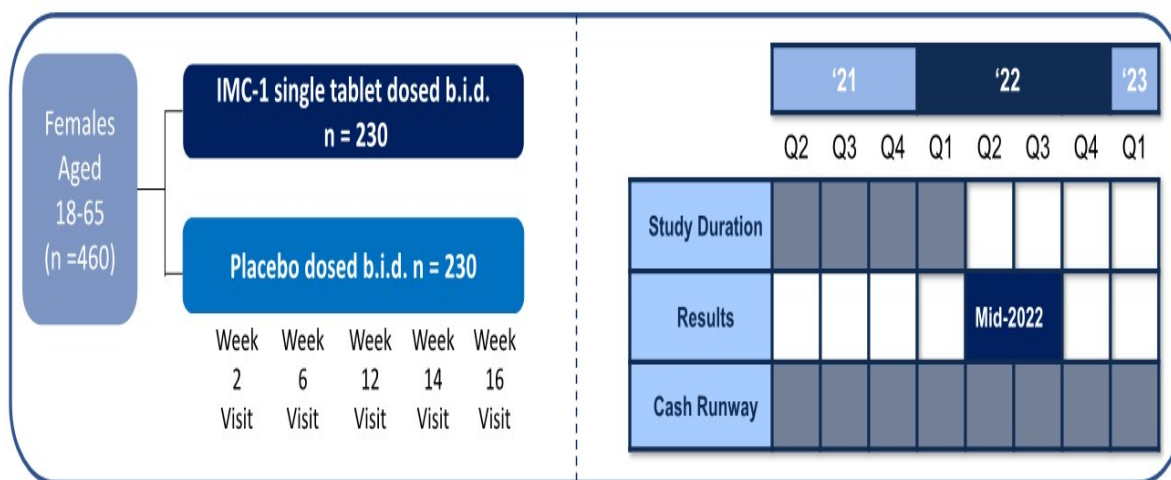
Primary Endpoint: Reduction in pain as measured by NRS 24 Hour Recall via daily electronic diary

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

FM Diagnosis using 2016 ACR criteria

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

Daily Assessments: 16 Weeks



IMC-1 Regulatory Considerations

- ❖ By combining proprietary doses of two approved drugs, our fixed dose combination development candidates has the advantage of being eligible for submission to the FDA for approval under Section 505(b)(2)
- ❖ IMC-1 Composition of Matter “Synergy” intellectual property protection to 2033
- ❖ Based on the significant unmet need in treating FM and positive Phase 2a FM data, IMC-1 has been granted FDA designation for fast-track review status
- ❖ Most products that are eligible for fast-track designation are also likely to be considered appropriate to receive a priority review
 - Priority review means that the goal for the FDA to review an application is six months, rather than the standard review of ten months under current PDUFA guidelines
- ❖ This unique approach enabled us to advance IMC-1 directly into a Phase 2a proof of concept study at a fraction of the cost of traditional drug development
- ❖ The Phase 2b and chronic toxicology studies are planned components of the registration package, supporting Phase 3 requirements

IMC-1 Pipeline Potential Extends to Other Functional Somatic Syndromes

FIBROMYALGIA

- IMC-1 Statistically Significant Reduction in Pain P2a
- FDA Fast Track Review Designation, Progressing to P2b

IRRITABLE BOWEL SYNDROME

- Univ. of AL GI Biopsy Data Confirm Active HSV-1 in IBS
- ROME IV IBS Assessment Criteria Places Increasing Focus on Pain

CHRONIC FATIGUE SYNDROME/ MYALGIC ENCEPHALITIS

- Viral infections identified as possible triggers of CFS/ME
- IMC-1 Statistically Significant Reduction in fatigue in FM P2a
- Fatigue most common symptom beyond 2 weeks after COVID-19 onset

Virios Therapeutics Inc Combination Antiviral Pipeline Includes 21 Issued Patents

Issued US IMC-1 Patents

- U.S. "Composition of Matter" Patents (US 8,809,351 & US 10,034,846) Drug-combination of famciclovir and celecoxib
- U.S. "Method-of-Use" Patent (US 9,040,546) Famciclovir + celecoxib for the treatment of FM (fibromyalgia), CFS or IBS
- U.S. "Method-of-Use" Patent (US 9,173,863) Method of dispensing famciclovir + celecoxib in a regimen to treat Functional Somatic Syndrome conditions
- U.S. "Composition of Matter" Synergistic Patent (US 10,251,853) Synergistic combination for total daily dose of famciclovir and celecoxib

Issued Foreign IMC-1 Patents

- European Patent (EP 2 811 833 & 2 965 759 – validated in 18 countries), Japan (JP 5855770 & 6422848), Australia (AU 2013217110), China (CN 104144606), Korea (KR 10-1485748) & Canada (2,863,812)

US Patents Covering Other Anti-Viral Combinations

- U.S. 9,682,051 (acyclovir/meloxicam)
- U.S. 8,623,882 (acyclovir/diclofenac)
- U.S. 9,259,405 (famciclovir/diclofenac)
- U.S. 9,642,824 (valacyclovir/diclofenac)
- U.S. 9,980,932 (valacyclovir/meloxicam)
- U.S. 10,543,184 (acyclovir/celecoxib)
- U.S. 10,632,087 (famciclovir/meloxicam)
- U.S. 11,096,912 (valacyclovir/celecoxib)

Capital Table as of June 30th 2021

	
Listing/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	20.0%

*Become Exercisable on December 16, 2021

**Weighted Avg. Exercise Price of \$9.31/share

***Includes officers and directors

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