

Filed Pursuant to Rule 433 Issuer Free Writing  
Prospectus dated November 25, 2020  
File No.: 333-248447

# VIRIOS

## Therapeutics

**New Scientific Paradigm Exploring  
HSV-1 Virus Activation as Potential  
Underlying Cause of Fibromyalgia and  
Other Chronic Conditions**

Investor Update

HSV-1 Virus

# Forward Looking Statements Disclaimer Free Writing Prospectus Disclaimer

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, statements regarding Virios Therapeutics Inc.'s expectations regarding the trading of its shares on the NASDAQ Capital Market and the timing and likelihood of success of future clinical trials. 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 and other risks and uncertainties are described more fully in the section titled "Risk Factors" in the final prospectus related to our initial public offering filed with the Securities and Exchange Commission ("SEC"). Forward-looking statements contained in this presentation are made as of this date, and we undertake no duty to update such information except as required under applicable law.

We have filed a registration statement (including a preliminary prospectus) with the SEC for the offering to which this communication relates. The registration statement has not yet become effective. Before you invest, you should read the preliminary prospectus in that registration statement (including the risk factors described therein) and other documents that we have filed with the SEC for more complete information about us and this offering. We encourage you to read the registration statement and the prospectus in full for more detailed information on the statistics, reports and clinical trials referenced in this presentation.

You may access these documents for free by visiting EDGAR on the SEC Web site at <http://www.sec.gov>. Alternatively, we or any underwriter participating in the offering will arrange to send you the prospectus if you contact ThinkEquity, a division of Fordham Financial Management, Inc., Prospectus Department, 17 State Street, 22<sup>nd</sup> Floor, New York, New York 10004, telephone: (877) 436-3673 or e-mail: [prospectus@think-equity.com](mailto:prospectus@think-equity.com).



# Offering Summary

<b>Issuer</b>	<b>Virios Therapeutics, Inc.</b>
<b>Expected Offering Size</b>	\$30,000,000
<b>Expected Price Range</b>	\$9.00 - \$11.00
<b>Shares Offered</b>	3,000,000 (450,000 over-allotment option)
<b>Listing / Symbol</b>	Nasdaq / VIRI
<b>Use of Proceeds</b>	<ul style="list-style-type: none"><li>• Execute IMC-1 fibromyalgia Phase 2b clinical trial</li><li>• IMC-1 chronic toxicology studies</li><li>• Manufacture investigational drug for the Phase 2b study &amp; chronic tox study<ul style="list-style-type: none"><li>• Scale clinical manufacturing process for Phase 3</li></ul></li><li>• Design irritable bowel syndrome proof of concept trial</li></ul>
<b>Sole Book-Runner</b>	ThinkEquity, a division of Fordham Financial Management, Inc.



# Virios Therapeutics Overview



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

Management Directly Involved In Launch of Lyrica® and Savella® for FM



**Greg Duncan**  
Chairman & CEO



**Rick Burch**  
President\*



**R. Michael Gendreau**  
MD, PhD  
CMO



**Ralph Grosswald**  
VP of Operations



**Angela Walsh**  
VP of Finance



Pharma Experience  
includes  
Notable Medicines



\*Mr. Burch will resign as President and will be appointed as a Director upon the completion of our corporate conversion.

# Experienced Board of Directors, Including Expertise Developing & Commercializing Leading Antiviral Therapies



**Rich Whitely,  
MD**

- Distinguished Professor Loeb Scholar Chair in Pediatrics, and Professor of Microbiology, Medicine and Neurosurgery, UAB
- Gilead's Board of Director
- Co-Founder & Co-Director, Alabama Drug Discovery Alliance
- 380 Publications
- Obama H1N1 Task Force
- Remdesivir was Originally Developed by Dr Whitely's team at UAB



**Abel De La Rosa,  
PhD**

- CEO, Director, co-founder of Antios Therapeutics
- Chief Scientific Officer of Drug Innovation Ventures at Emory
- Led Bus Dev for Pharmasset through acquisition by Gilead Sciences (NASDAQ: GILD) for \$11.5 billion in 2012
- Provided Business and Scientific Leadership for Development Programs for the Treatment of HIV, Hepatitis B and C, including Sofosbuvir



**John Thomas,  
CPA**

- CorMatrix Cardiovascular DemeRx, 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.
- Seven-time winner of Pharma Voice's top 100 leaders in healthcare
- Executive roles at Pharmacia, Pfizer, Wyeth, Biovail and Publicis Health



**Skip Pridgen, MD  
Founder**

- Company Founder
- Board-certified surgeon practicing with Tuscaloosa Surgical Associates, P.C.
- Spent nearly 20 years searching for effective treatments in IBS, FM, and CFS/ME
- Served as a physician and surgeon in the United States Navy

The board also includes current executives, Greg Duncan and Rick Burch



# Scientific Advisory Board Includes Top Global FM Thought Leaders

## **Daniel J. Clauw, MD**

Chair: Professor of Anesthesiology, Medicine (Rheumatology) and Psychiatry at the University of Michigan

Director of the Chronic Pain and Fatigue Research Center

## **Lesley M. Arnold, MD**

Professor of Psychiatry and Behavioral Neuroscience at the University of Cincinnati College of Medicine

## **Dedra S. Buchwald, MD**

Professor in the Department of Epidemiology at the University of Washington School of Medicine

## **Joel D. Baines, VMD, PhD**

Joel Baines is dean of the Louisiana State University, School of Veterinary Medicine

## **Michael Camilleri, MD**

Professor of Medicine (Gastroenterology), Pharmacology and Physiology at Mayo Clinic

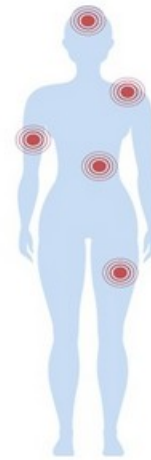
# Fibromyalgia Disease Overview

## 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  $\geq 3$  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
- An Estimated 40% of FM Patients are Treated with Opioids
  - Opioid-treated FM Patients have Worse Outcomes than Those Not on Opioids

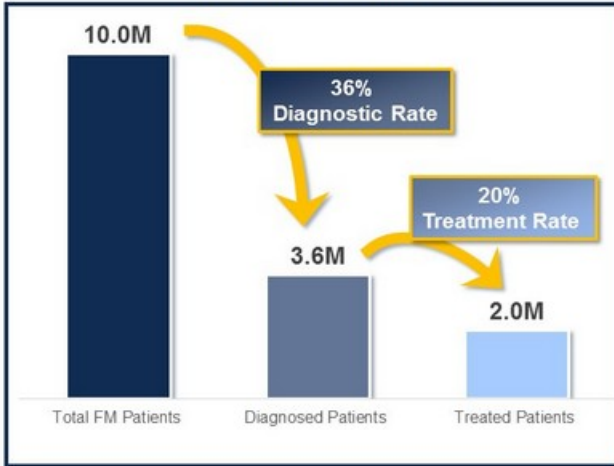


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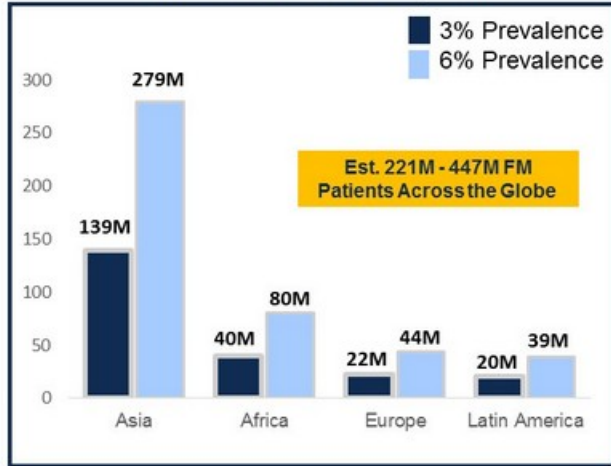


# The Fibromyalgia Market is Large and Poised for Growth if Better Therapeutic Options Emerge

Significant US FM Market  
Growth Potential Still Exists

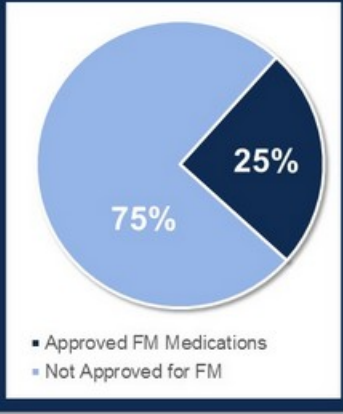


Worldwide FM Prevalence Ranges  
From 3%-6% of the Population

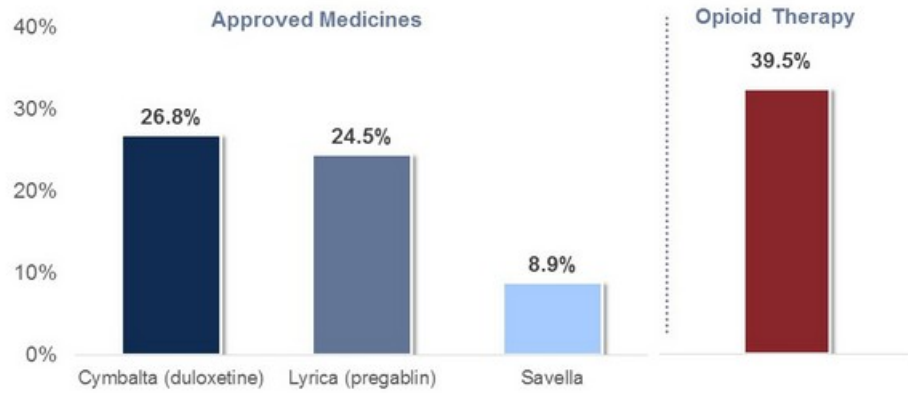


# Polypharmacy and Utilization of Unapproved Therapies Demonstrates Significant Unmet Need

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

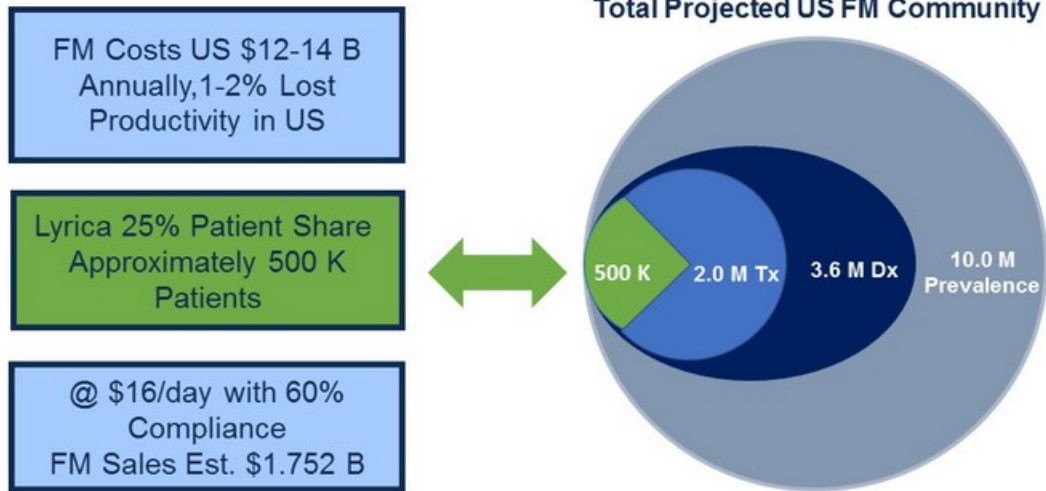



### Share of US Treated FM Patients by Therapy



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



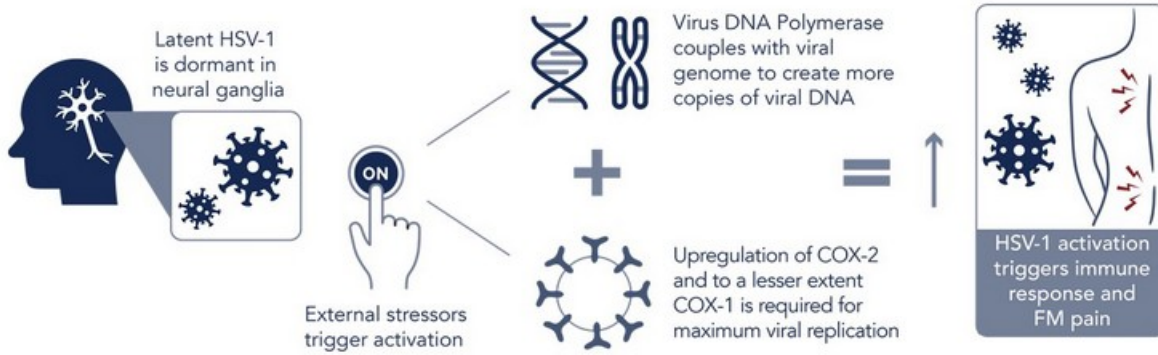
The background of the slide is a composite image. On the left, there is a close-up, blue-tinted microscopic view of several HSV-1 virus particles, which are spherical with a textured surface. On the right, there is a faint, blue-tinted image of human hands, with the fingers spread, suggesting a connection between the virus and human interaction or infection.

**Virios Discovery - Reactivation  
of Latent HSV-1 Virus Triggers  
Overactive Immune Response,  
and Manifestation of FM**

HSV-1 virus

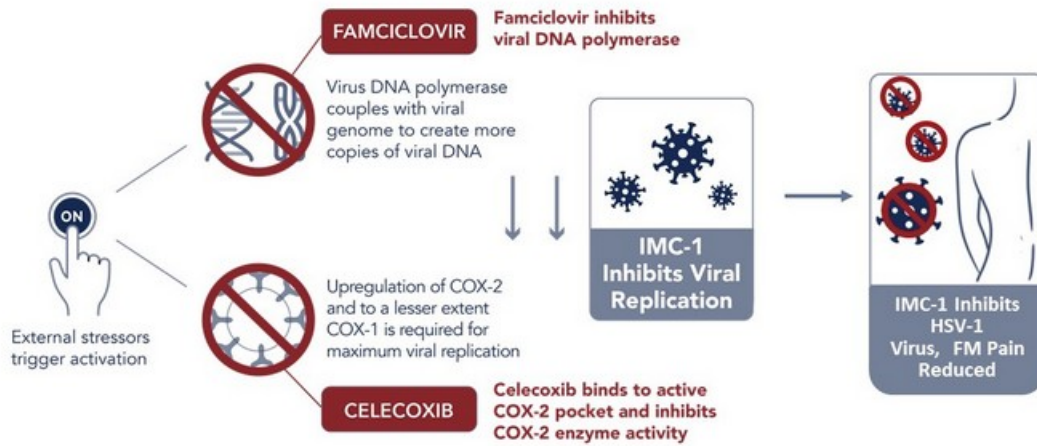
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# Discovery Implicates Dormant HSV-1 Reactivation Triggers Immune Response and Manifestation of Fibromyalgia



More Than 3.7 Billion People Under the Age of 50 – or 67% of the Population are infected with Herpes Simplex Virus Type 1 (HSV-1), According to WHO

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



IMC-1 is a Proprietary Fixed Dose Combination of Famiciclovir and Celecoxib that Cannot be Replicated Using Available Generics

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

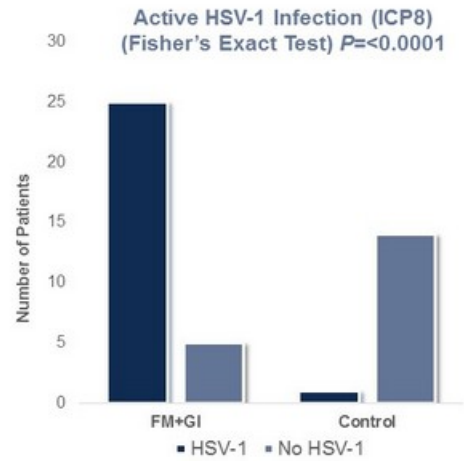
## *Viral GI Tissue Study:*

### **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



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The background of the slide features a blue-tinted microscopic image of HSV-1 virus particles, which are spherical with a textured surface. A faint, glowing handprint is overlaid on the image, centered in the upper half. The text is positioned to the right of the handprint.

**IMC-1's Potential Identified  
in Statistically Significant  
Phase 2a Trial Results**

HSV-1 virus

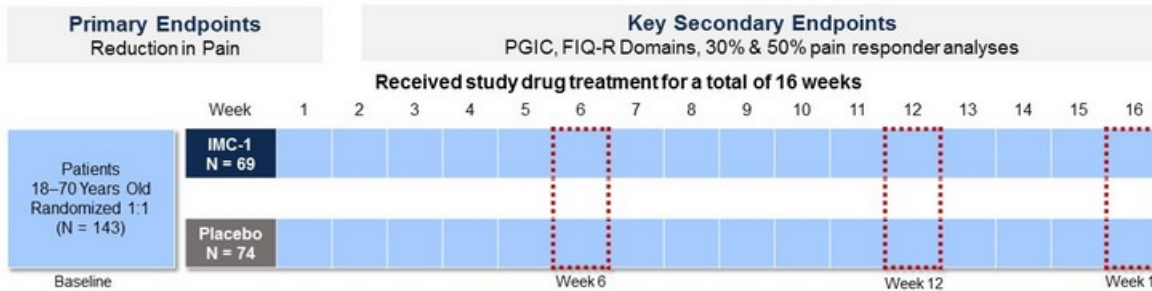
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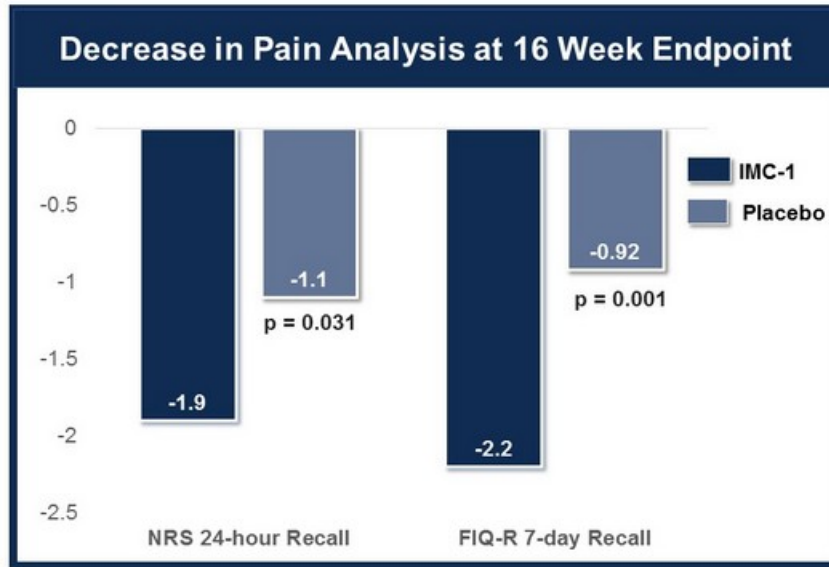
# IMC-1: Phase 2a Clinical Proof of Concept Trial

## Design Summary:

- Randomized, Double-blind, Multi-center, Placebo-controlled
- IMC-1 (famciclovir + celecoxib) vs Placebo, Dosed BID
- Famciclovir Dose Not Optimized
- Diagnosis of Fibromyalgia Using 2010 ACR, Assessments at Weeks 6, 12 and 16
- Stop Taking NSAIDs at Randomization
- 7-day Washout of FM Drugs and Opioids



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



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

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



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

Category	Placebo	IMC-1	IMC-1 Difference
Randomized	74	69	
Completed 16 weeks on study drug	45 (60.8%)	57 (82.6%)	22%
<b>Discontinuation reasons:</b>			
Adverse event <span style="background-color: #90EE90; padding: 2px;">(p=0.012)</span>	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

# IMC-1 Phase 2b Design Using Optimized IMC-1 Dosage

**Design:** Randomized, double-blind, multi-center, placebo-controlled trial  
**Primary Endpoint:** Reduction in pain

**Secondary Endpoints:** Change in fatigue, sleep disturbance, global health status, and patient functionality

**FM Patients**  
2016 ACR criteria

**Age**  
18 - 70

**Sample Size**  
460 (~230/arm)

**Treatments**  
IMC-1 vs  
Placebo

**Daily Assessments**  
16 Weeks

	2021				2022	
	Q1	Q2	Q3	Q4	Q1	Q2
Manufacture Clin Supply						
Study Start-up						
Enrollment						
Study Duration						
P2b Topline Results						

Chronic Toxicology Study Will Run in Parallel with the P2b Clinical Trial



# IMC-1 Pipeline Potential Extends to Other Functional Somatic Syndromes

## FIBROMYALGIA

- IMC-1 Statistically Significant P2a FM data
- FDA Fast Track Review Designation

## IRRITABLE BOWEL SYNDROME

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

## CHRONIC FATIGUE SYNDROME/ MYALGIC ENCEPHALITIS

- Viral infections possible triggers of CFS/ME
- IMC-1 Statistically Significant Reduction in Fatigue

# Virios Has 20 Existing Patents that All Provide Protection to 2033

## Issued Patents (Expire 6 Feb 2033):

### Issued US IMC-1 Patents

- U.S. "Composition of Matter" Patents (US 8,809,351 & US 10,034,846) Drug-combination of famciclovir + celecoxib
- U.S. "Method-of-Use" Patent (US 9,040,546) Famciclovir + celecoxib for the treatment of FM, 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 + celecoxib

### Issued Foreign IMC-1 Patents

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

### Patents Covering Other Anti-Viral Combinations

- US 9,682,051 (acyclovir/meloxicam)
- US 8,623,882 (acyclovir/diclofenac)
- US 9,259,405 (famciclovir/diclofenac)
- US 9,642,824 (valacyclovir/diclofenac)
- US 9,980,932 (valacyclovir/meloxicam)
- US 10,543,184 (acyclovir/celecoxib)
- US 10,632,087 (famciclovir/meloxicam)
- EP 2 965 759 (all combinations)



## Capitalization Table - Pro Forma Pre-Offering

<b>Common Shares<sup>1</sup></b>	<b>5,125,000</b>
<b>Warrants<sup>2</sup></b>	<b>134,663</b>
<b>Options<sup>3</sup></b>	<b>528,125</b>

<sup>1</sup>Includes underlying shares for conversion of convertible notes and 292,500 of vested non-qualified options assuming a \$10.00 offering price, the mid-point of the expected price range.

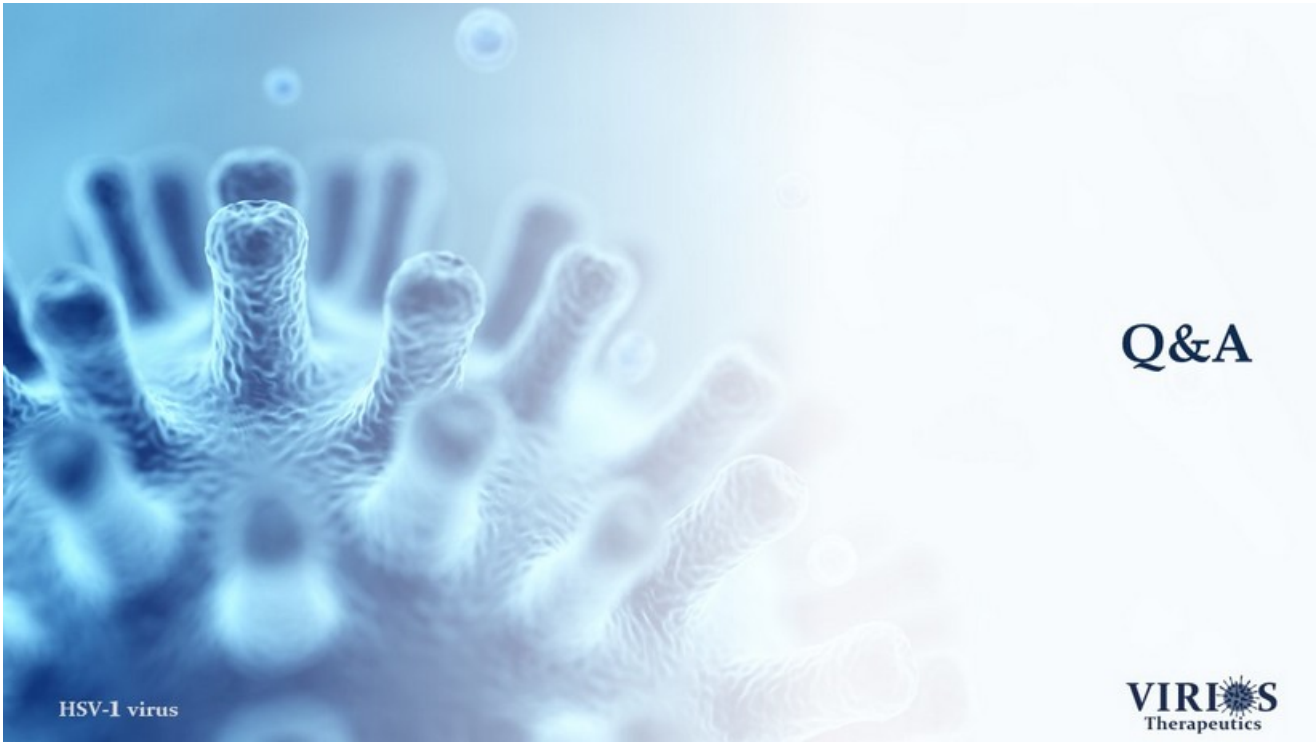
<sup>2</sup>Warrants are exercisable in cash within 30 days of pricing at an exercise price of \$7.80 assuming a \$10.00 offering price.

<sup>3</sup>Includes options issued in connection with this offering equal to 6.5% of outstanding shares assuming a \$10.00 offering price, the mid-point of the expected price range.



# Virios Therapeutics Summary





## Q&A

HSV-1 virus

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