

# VIRIUS

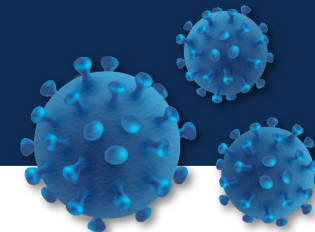
Therapeutics

*Novel, synergistic combination antiviral approach delivers clinical benefits for patients suffering from suspected viral mediated illness*

**Nasdaq: VIRI**

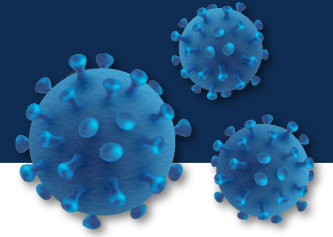


# Forward Looking Statements



- 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/A for the year ended December 31, 2023 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.
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- 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>.

# Experienced Team with Extensive Drug Development and Commercialization Experience



## 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, Biovail 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., MiMedx Group, Inc., DARA BioSciences, GMP Companies
- MRI Interventions, EnterMed, Inc.,
- Medicis Pharm Corp., CytRx Corp



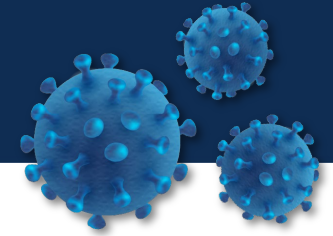
**Skip Pridgen, MD**  
VIRI Founder

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

## Management's Brand Development & Commercialization Experience Includes:

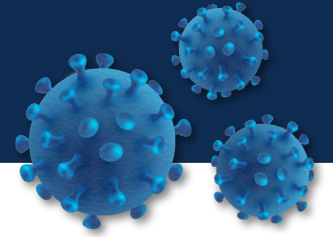


# Virios Therapeutics, Inc. Summary



- ❖ **Two novel, late-stage clinical stage development assets:**
  - ❖ **IMC-2 (valacyclovir + celecoxib) Phase 2 Long-COVID study ongoing:**
    - ❖ Proof of concept completed in study 2023, new IP filed with protection potential to 2044
    - ❖ We have clarity from FDA on the development requirements associated with advancing IMC-2 into Phase 2 development as a treatment for Long-COVID symptoms
    - ❖ Three-arm, Phase 2 investigator-initiated study of IMC-2 enrolling, topline data expected summer 2024
  - ❖ **IMC-1 (famciclovir + celecoxib) ready for Phase 3 as treatment for fibromyalgia (FM):**
    - ❖ Phase 2a and Phase 2b in FM
    - ❖ FDA agreement to enter Phase 3 post EoP2 meeting
    - ❖ Exploring Phase 3 partnership and extended-release dosage formulation to extend IP

# Herpes Viruses are Life Long Chronic Infections and Can be Reactivated from a Dormant to Active State



Immune System Controls  
Primary Infection

Age, Stress, Injury or Infection  
(e.g. Covid) Weakens Immune  
System, Virus Reactivates

**Primary Herpes Infection  
Earlier in Life**

**Virus Converts Back into a  
Dormant State**

**Reactivated Herpes Conditions  
Triggers Inflammation**

**Varicella Zoster (Chicken Pox)**

Fever, tired, headache, stomachache, skin rash with blisters, bumps filled with liquid (**>95% American Adults**)

Establishes latency in neurons in the peripheral ganglia

**Shingles**

Skin sensitivity, tingling, itching, pain, rash, blisters  
Post Herpetic Neuralgia (PHN), vasculopathy, myelitis and focal motor weakness (**15% > risk with COVID**)

**Epstein-Barr (Mononucleosis)**

Fever, cough, sore throat, fatigue, malaise, headache  
Affects teenagers, most cases are asymptomatic (**>90% World**)

Establishes latency mainly in B cells and cannot ever be eradicated

**FM & Long-COVID**

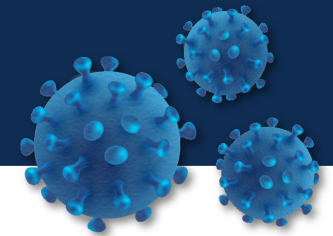
Pain, fatigue, brain fog, post exertional malaise, heart palpitations, orthostatic hypotension, dizziness, shortness of breath, headache, sleep problems, diarrhea

**Herpes Simplex 1 (HSV-1)**

Affects mouth/face ULong-COVIDers, pain, blisters, sores  
Most contract during childhood.  
Most asymptomatic (**67%-80% World**)

Neurotropic virus that establishes a life-long latent infection in the trigeminal ganglia

# IMC-1 and IMC-2 Deliver Consistent Efficacy Across Multiple Clinical Studies



Endpoint/ Study	Placebo/Control CFB	IMC-1/ IMC-2 CFB	Contrast	P Value
<b>PROMIS Fatigue - NIH Patient Reported Outcomes Measurement Information System</b>				
P2A (Fam/Cel) FM Patients	-4.15	-7.62	-3.47	<b>0.020</b>
P2B (Fam/Cel) New FM Patients	-1.94	-5.64	-3.70	<b>0.001</b>
P1 (Val/Cel) Long-COVID	-0.34	-7.24	-6.90	<b>0.008</b>
<b>NRS Pain – Numerical Rating Scale 0-10</b>				
P2A (Fam/Cel) FM Patients	-1.05	-1.85	-0.80	<b>0.031</b>
P2B (Fam/Cel) New FM Patients	-1.02	-1.69	-0.67	<b>0.016</b>
P1 (Val/Cel) Long-COVID	0.32	-1.14	-1.45	<b>0.041</b>
<b>Global Health: Percentage of patients with at least a 2 degree improvement on the PGIC scale*</b>				
P2A (Fam/Cel) FM Patients	19%	33%	14%	<b>0.040</b>
P2B (Fam/Cel) New FM Patients	20%	38%	18%	<b>0.010</b>
P1 (Val/Cel) Long-COVID*	12%	55%	43%	<b>0.006</b>

\*- PGIC responder calculation for P1 is based on 3 degrees of improvement vs. 2 degrees in PRID studies

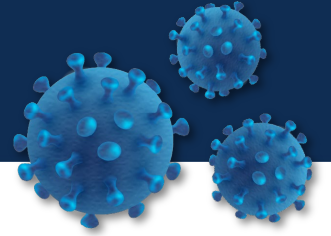


*IMC-2 for Long-COVID (in Phase 2)*

**Nasdaq: VIRI**



# Long-COVID Represents a Major Unmet Medical Need

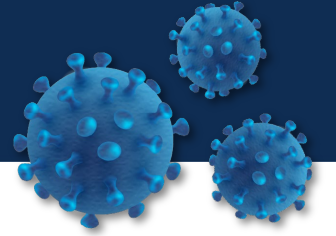


- ❖ Center for Disease Control (CDC) Long-COVID diagnosis criteria: New, recurring or continuation of symptoms  $\geq$  4 weeks after acute COVID infection
  - ❖ Up to 30% of Long-COVID patients were asymptomatic during acute COVID illness
- ❖ A 2022 CDC estimate revealed 3.4% of adults exhibited active Long-COVID sequelae, representing 11.2M US citizens
  - ❖ Up to 6 million children and 1 in 10 pregnant women develop Long-COVID
  - ❖ Hospitalized are more susceptible, but even those with mild cases can experience Long-COVID
  - ❖ Updated data from 2024, the CDC and National Center for Health Statistics census surveys found that
    - ❖ Long-COVID Rates are increasing
    - ❖ 17.6% of all adults in the US have ever experienced Long-COVID (44 million people)
- ❖ Most notable Long-COVID symptoms include fatigue and post exertional malaise
- ❖ Majority of COVID morbidity is associated not with acute COVID, but with Long-COVID

Sources: Anthony L. Komaroff and W. Ian Lipkin, *Frontiers in Medicine*, June 2023; Ford et al, *CDC Morbidity/Mortality Weekly*, 2023; *NCHS Data Brief*, 2023; Cutler, *Harvard Kennedy Center Review*, 2022; Perumal, 2023; Gearhart-Serna, Ph.D, *NIH Research Matters*, 2022; Rao et al, *Pediatrics*, 2024;  
<https://www.medscape.com/viewarticle/new-data-long-covid-cases-surge-2024a10005vv?src=>  
<https://www.cdc.gov/nchs/covid19/pulse/long-covid.htm>

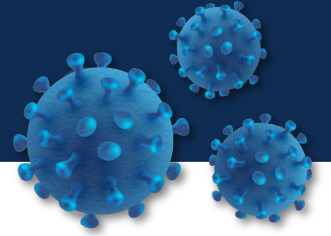


# Logical Approach to Treating Long-COVID



- ❖ Recent studies support concept that reactivated herpes virus infection leads to Long-COVID illness, not residual SARS-CoV-2 virus after the acute infection
- ❖ No approved treatments for Long-COVID illness
  - ❖ Only approved COVID treatment Paxlovid failed to improve Long-COVID sequelae
- ❖ Reactivated herpes viruses, such as Epstein-Barr virus (EBV) and HSV-1, are associated with fatigue and cognitive dysfunction, the predominant symptoms of Long-COVID
- ❖ Nucleoside analogs (i.e. valacyclovir and famciclovir) suppress herpesvirus reactivation

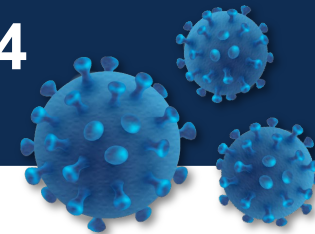
# IMC-2 Long-COVID Study Exploratory Study



- Study Supported by Unrestricted Investigational Grant to Bateman Horne Center (BHC)
- Patients were recruited from the BHC database, website and Utah Long Haulers Facebook group

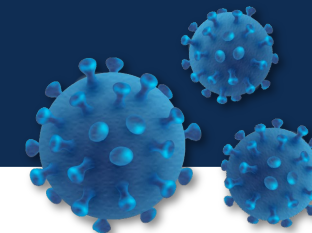
<b>Valacyclovir + Celecoxib Treated Patients n=22</b>	<b>Matched Controls n=17</b>
<ul style="list-style-type: none"><li>• All female, mean age = 43, mean duration of Long-COVID symptoms at enrollment = 2.0 years</li><li>• 86% SARS CoV2 vaccination rate</li><li>• Washed out of NSAIDs</li></ul>	<ul style="list-style-type: none"><li>• No placebo</li><li>• Matched controls based on treatment group enrolled participants</li><li>• All female, mean age = 47, mean duration of Long-COVID symptoms at enrollment = 2.1 years</li><li>• 82% SARS CoV2 vaccination rate</li><li>• No wash out</li></ul>

# Val/Cel Combination vs Control in Long-COVID Patients at Week 14



Study Endpoints	P-Value
NIH PROMIS Fatigue T-Score	0.008
NRS Fatigue 0-10 Scale	<0.001
NRS Pain 0-10 Scale	0.041
PGIC 1-7 (7 is best)	0.022
PGIC 0-10 (0 is best)	0.019
OISAS-Orthostatic Intolerance Symptoms Assessment Scale	0.002
OIDAS-Orthostatic Intolerance Daily Activity Scale	<0.001
HADS Depression Scale	0.059
HADS Anxiety Scale	0.023

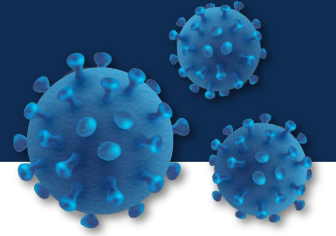
# Safety: Val/Cel vs Control in Long-COVID Patients



System Organ Class	Control	Val/Cel
Preferred name	(N=17)	(N=21)
Nausea	0 (0.0%)	6 (28.6%)
Headache	3 (17.6%)	3 (14.3%)
Back Pain	0 (0.0%)	3 (14.3%)
Upper respiratory tract infection	1 (5.9%)	2 (9.5%)
Dizziness	1 (5.9%)	2 (9.5%)
Fatigue	1 (5.9%)	2 (9.5%)
Myalgia	2 (11.8%)	1 (4.8%)
Pain in Extremity	1 (5.9%)	1 (4.8%)
Cough	1 (5.9%)	0 (0.0%)
Nasal Congestion	1 (5.9%)	0 (0.0%)
Oropharyngeal Pain	1 (5.9%)	0 (0.0%)
Sinus Congestion	1 (5.9%)	0 (0.0%)
Hypertension	1 (5.9%)	0 (0.0%)

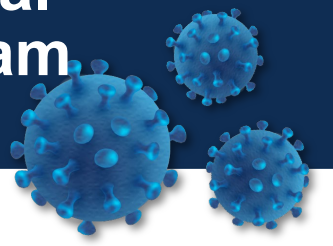
- Treatment with Val/Cel was extremely well tolerated, with an observed safety profile consistent with the known safety profiles of valacyclovir and celecoxib, nausea being the most common adverse event.
- There were no serious adverse events observed in this study and only one treated patient discontinued treatment due to worsening fatigue, considered possibly related to Val/Cel treatment.

# Bateman Horne Center 202 PASC Study Status

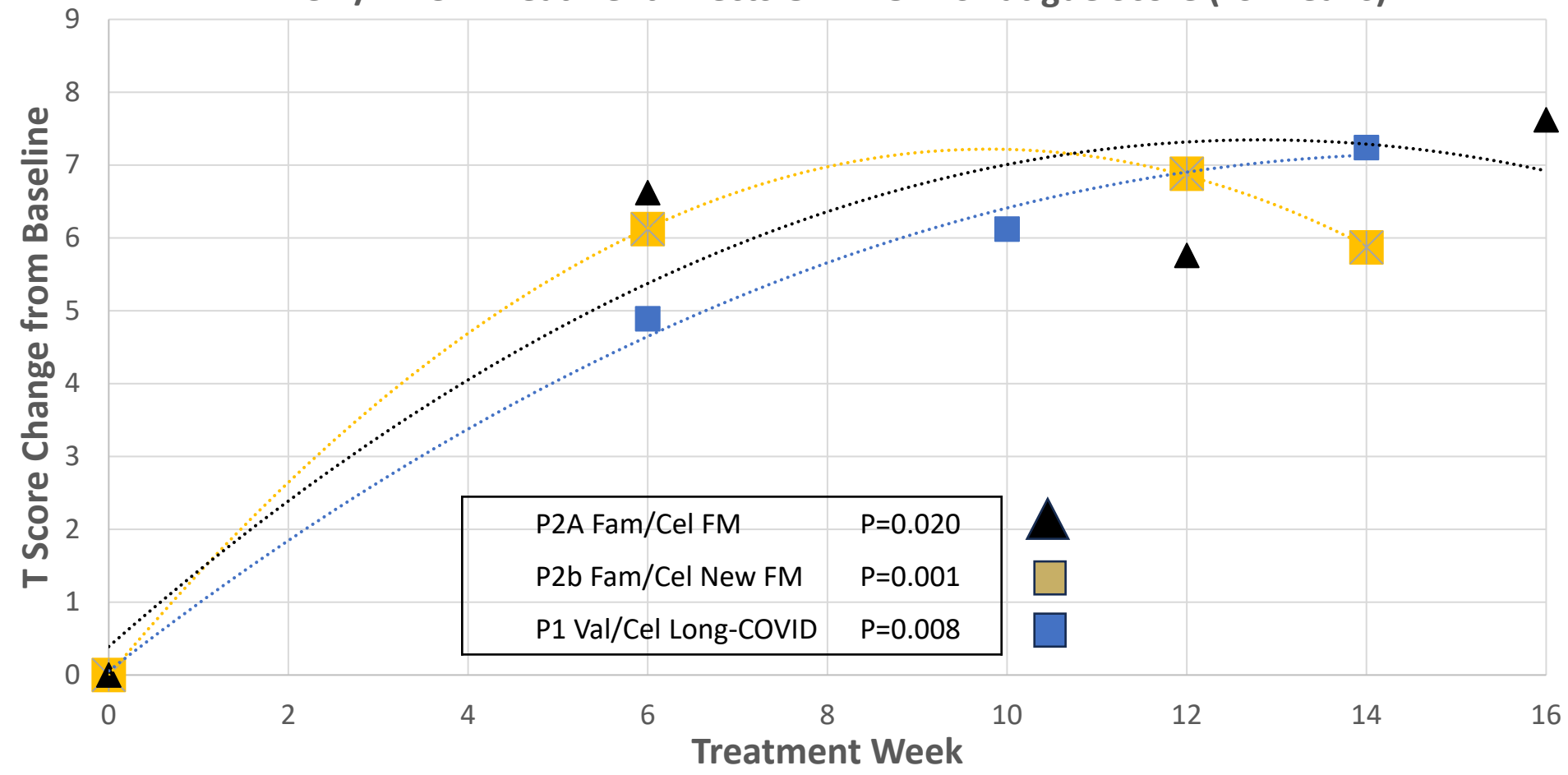


- ❖ Study run by Bateman Horne Center, Salt Lake City, Utah
  - ❖ Second IRB approved study supported by Virios via unrestricted, investigator-initiated grant
  - ❖ Dr. Lucinda Bateman, MD, a recognized leader in both Long-COVID and fatigue related clinical research, serves as BHC 202 primary investigator
- ❖ Planned enrollment commenced in December 2023: 3 Arms 1:1:1 randomization, double blinded and randomized study:
  - ❖ Val/Cel 750/200 BID (1.5g/400mg per day)
  - ❖ Val/Cel 1500/200 BID (3g/400mg per day)
  - ❖ Placebo capsules
- ❖ Primary Endpoint: fatigue reduction
- ❖ Secondary Endpoints assessments: sleep, orthostatic symptoms, anxiety, depression and overall health
- ❖ Data Summer 2024

# IMC-1/IMC-2 Deliver Significant Reduction in Fatigue Across all Clinical Studies, Highlights Potential for Broader Fatigue Development Program



IMC-1/ IMC-2 Treatment Effects On PROMIS Fatigue Score (LS Means)



**Potential Research Targets:**

- Myalgic Encephalitis (ME)/Chronic Fatigue Syndrome (CFS)
- Fatigue associated with Multiple Sclerosis (MS)

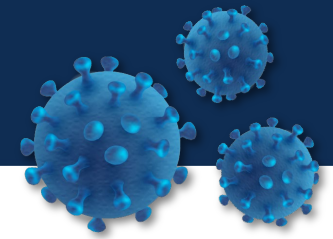


*IMC-1 for Fibromyalgia (Phase 3)*

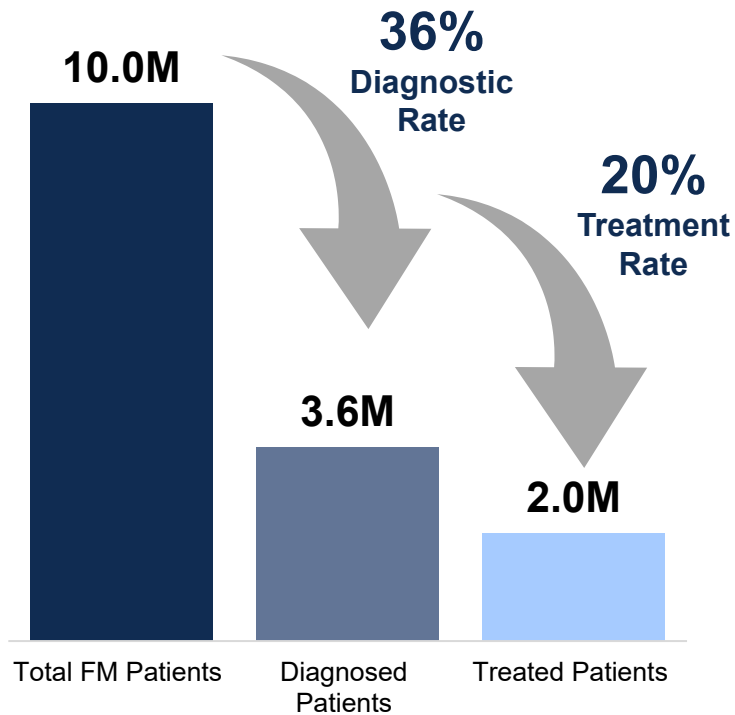
**Nasdaq: VIRI**



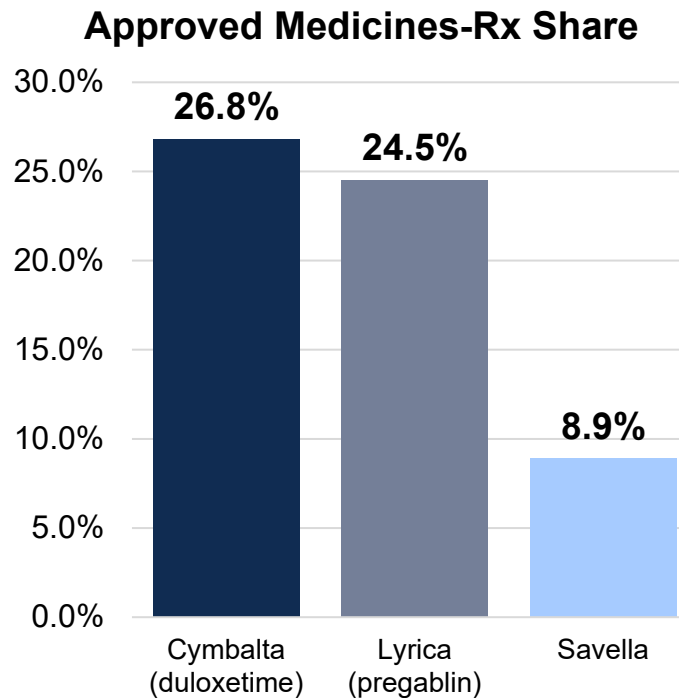
# Fibromyalgia Market Dynamics: Addressable Patients, Current Treatments and Market Size



## Addressable Patients in the US



## Global FM Market Sales Estimated at \$1.9B in 2019



## Virios Market Focus

1. Patients who are not on any existing therapy, 1.6M patients
2. Patients who discontinue current therapy (Lyrica, Cymbalta and Savella) within 1 year due to tolerability issues, 25.1% of 2M = 502K patients

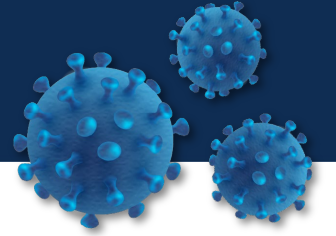
Virios has ability to target ~2.1M patients who are not on any current therapy, excluding “add-on” therapy opportunity

Significant commercial potential (~\$2B)

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 Phase 3 Study Designs Reviewed with FDA



## Pharmacokinetic/Food Effect Study

### Study 1 - 301

- ❖ Head-to-Head IMC-1 vs Placebo (n=320)
- ❖ 1:1 Randomization 160 in each group
- ❖ Primary Endpoint – Reduction in Pain at 12 Weeks

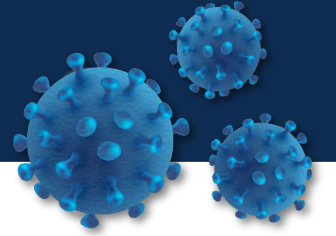
### Study 2 - 302

- ❖ Multifactorial Study of IMC-1 vs Placebo vs Famciclovir reference drug tablet vs Celecoxib reference drug capsule (n=640)
- ❖ 1:1:1:1 Randomization – 160 each group
- ❖ Primary Endpoint – Reduction in Pain at 12 Weeks

### Long-COVID Term Extension - 309

- ❖ Patients from both studies above will roll over into a long-term extension study
- ❖ Treatment with IMC-1 for a year (n= 300 subjects at 6 months and 100 at 1 year)

# Moving Forward



- ❖ Preparing to advance IMC-2 Phase 2 Long-COVID program independently
- ❖ We are actively exploring partnership opportunities:
  - ❖ Phase 3 IMC-1 for FM
  - ❖ Complementary opportunities to build shareholder value under VIRI team leadership
    - ❖ Pain management and anti-infective opportunities
- ❖ We will report material progress on any proposed partnership in a timely manner