

## **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," 'solud, "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.

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### Free Writing Prospectus

- This presentation highlights basic information about us and the proposed offering. Because it is a summary, it does not contain all of the information that you should consider before investing. We have filed a registration statement (including a preliminary prospectus supplement and the accompanying prospectus) with the SEC for the offering to which this presentation relates. Before you invest, you should read the prospectus supplement and the accompanying prospectus in the registration statement (including the risk factors described therein) and other documents we have filed with the SEC for more complete information about us and the offering.
- You may access these documents for free by visiting EDGAR on the SEC Web site at http://www.sec.gov. The preliminary prospectus supplement is available 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, Prospectus Department, 17 State Street, 41st Floor, New York, New York 10004, telephone: (877) 436-3673 or e-mail: prospectus@think-equity.com.
- This presentation shall not constitute an offer to sell, or the solicitation of an offer to buy, nor will there be any sale of these securities in any state or other jurisdiction in which such offer, solicitation or sale would be unlawful prior to the registration or qualification under the securities laws of such state or jurisdiction. The offering will only be made by means of a prospectus supplement and related base prospectus.

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### 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

ALTEA Coltaxeys



Ralph Grosswald SVP of Operations



#### **DIRECTORS**



#### Rich Whitley, MD

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



#### Rick Keefer

- 30-year Pharma industry veteran with broad-based experience in leading commercial operations. Executive roles at Pharmacia, Pfoer, Wyeth, Bioval and Publicis Health Seven-time of the Programment of the P









#### John Thomas, CPA

- CorMatrix Inc., MiMedx Group Inc., DARA BioSciences, GMP



#### Rick Burch

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



#### 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:





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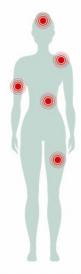
4

## Fibromyalgia Syndrome Overview



#### **FM 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
  - · One in two patients miss work
- Estimates Suggest as Many as 40% of FM Patients are Treated with Opioids

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



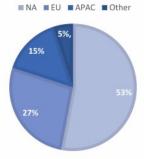
5

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# The Global Fibromyalgia Market is Large but Dissatisfied, Poised for Growth if Better Therapeutic Options Emerge

## Significant Global FM Commercial Opportunity

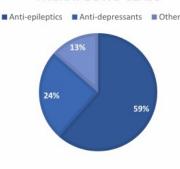
#### GLOBAL FM SALES BY REGION



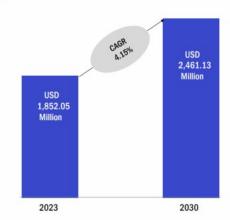
Source: Verified Market Research, FM Report, 2021

Anti-epileptics and Anti-depressants are Dominant Treatments

## GLOBAL SALES BY THERAPEUTIC CLASS



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



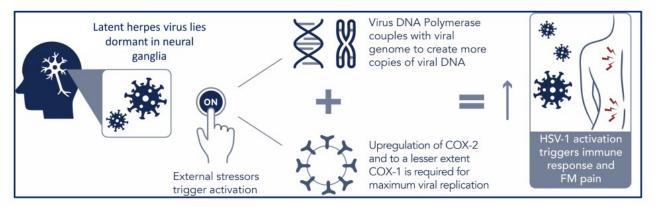
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6

### Hypothesis Implicates Dormant Herpes Virus Reactivation Triggering Dysfunctional Immune Response and/or FM Severity





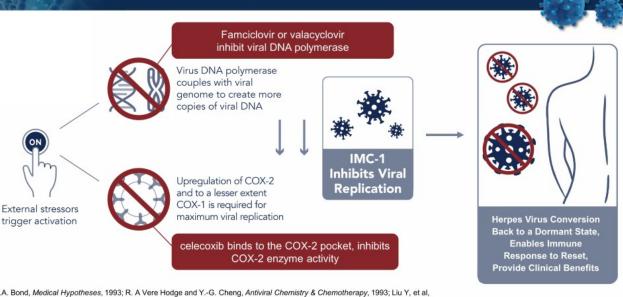
Source: P.A. Bond, Medical Hypotheses, 1993; R. A. Vere Hodge and Y.-G. Cheng, Antiviral Chemistry & Chemotherapy, 1993; Kaufman et al, IOVS, 2005; Liu Y, et al, Scientific World Journal, 2014; Higaki S, et al Current Eye Research, 2009; Francisco Javier Ibañez et al, Frontiers in Microbiology, 2018

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

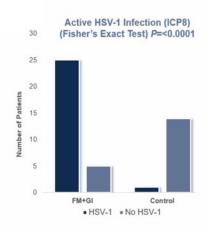


Source: P.A. Bond, Medical Hypotheses, 1993; R. A Vere Hodge and Y.-G. Cheng, Antiviral Chemistry & Chemotherapy, 1993; Liu Y, et al, Scientific World Journal, 2014; Higaki S, et al Current Eye Research, 2009; Francisco Javier Ibañez et al, Frontiers in Microbiology, 2018

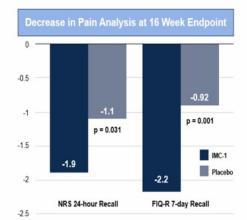
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## Purposeful Research Approach Focused on Herpes Virus Inhibition Demonstrates IMC-1 Clinical Potential in FM

GI Biopsy Study Confirms Herpes Infection in Somatic Syndrome Disorders



Phase 2a Clinical Study Identifies Potential of IMC-1



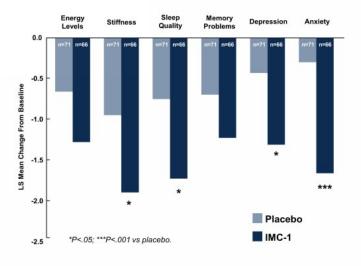
Source: C. Duffy, et al, Infection, 2022; W. Pridgen et al, Journal of Pain 2017; Virios Therapeutics, Inc, Data on File, 2022

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9

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## Oral IMC-1 Demonstrated Clinical Benefits on a Variety of FM Related Outcomes Measures



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

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## **FORTRESS Clinical Trial Design**

#### **Design Summary:**

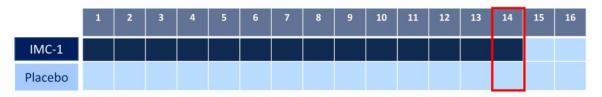
- 425 Female Patients Enrolled 18-65 Years of Age, 422 ITT population
- 1:1 IMC-1 (675mg famciclovir + 180mg celecoxib) vs Placebo, Dosed BID
- · Double-blind, 41 US Research Centers
- Diagnosis of Fibromyalgia Using 2016 ACR Criteria

#### Primary Endpoints: 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



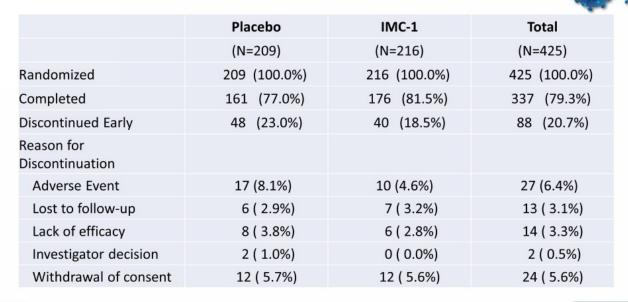
Prospectively Defined Primary Endpoint Analysis

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1

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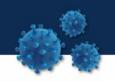
## **FORTRESS Disposition**



12

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## **FORTRESS Adverse Events**

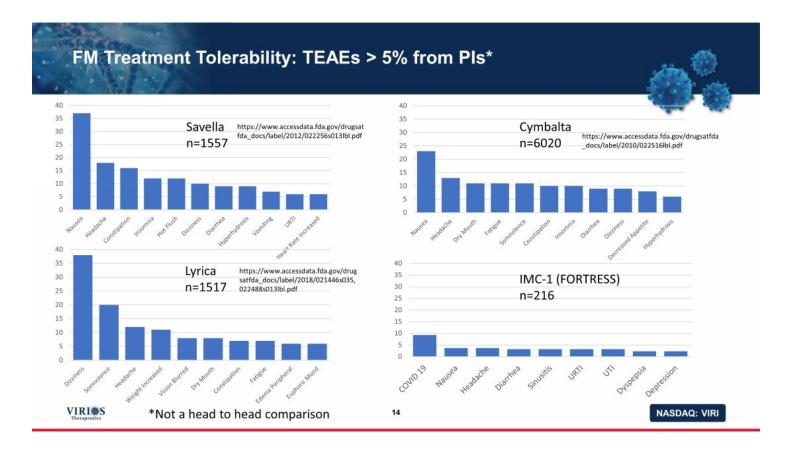


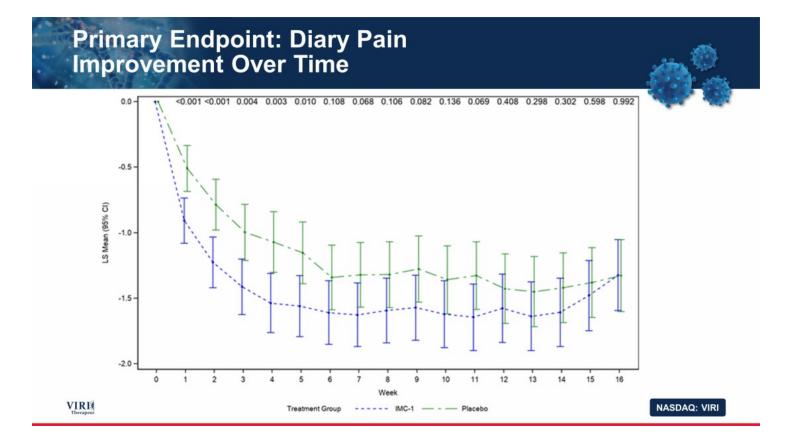
AEs in >2% of IMC-1 Patients	Placebo IMC-1		Total	
Preferred Term	(N=208)	(N=216)	(N=424)*	
	110 (52.9%)	121 (56.0%)	231 (54.5%)	
COVID-19	17 ( 8.2%)	20 ( 9.3%)	37 ( 8.7%)	
Nausea	4 ( 1.9%)	8 ( 3.7%)	12 ( 2.8%)	
Headache	12 ( 5.8%)	8 ( 3.7%)	20 ( 4.7%)	
Sinusitis	7 ( 3.4%)	7 ( 3.2%)	14 ( 3.3%)	
Upper respiratory tract infection	1 ( 0.5%)	7 ( 3.2%)	8 ( 1.9%)	
Urinary tract infection	10 ( 4.8%)	7 ( 3.2%)	17 ( 4.0%)	
Diarrhoea	7 ( 3.4%)	7 ( 3.2%)	14 ( 3.3%)	
Dyspepsia	3 ( 1.4%)	5 ( 2.3%)	8 ( 1.9%)	
Depression	2 ( 1.0%)	5 ( 2.3%)	7 ( 1.7%)	

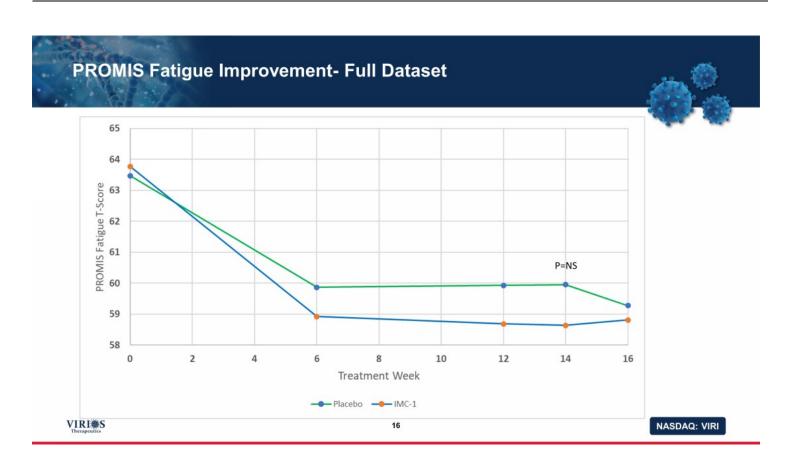
<sup>\*</sup> Note: safety population was n=424 due to one patient who was randomized but never received drug

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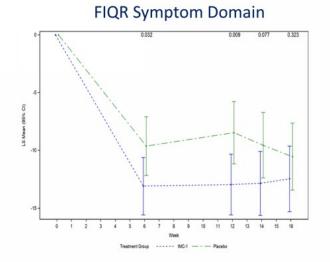
13

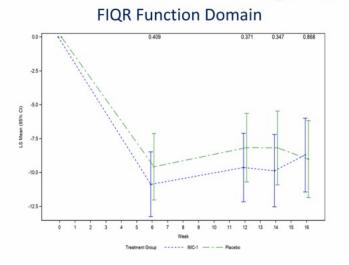






## FIQR Symptoms & Function Improvement





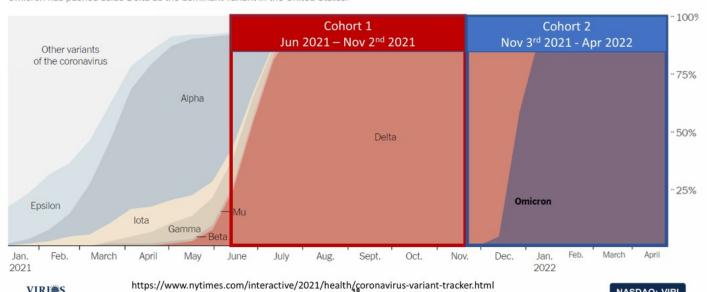
17 VIRI#S

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## **Enrollment Timing and COVID-19 Variants**

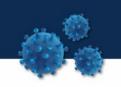
#### Waves of Variants in the United States

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



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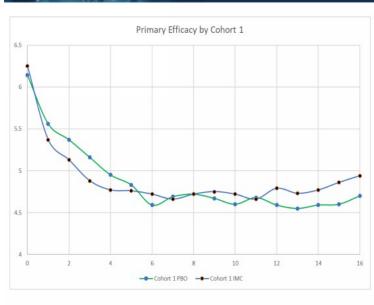
## **Cohort 1 Versus Cohort 2 Analyses**

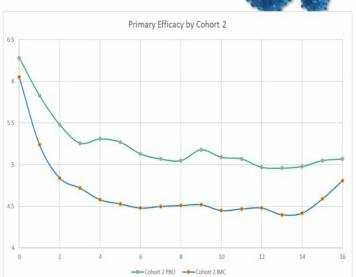


Primary Endpoint	Enrollment Dates		Placebo Week 14	IMC-1 Baseline	IMC-1 Week 14	CFB	P Value
Cohort 1 n=208	June '21 - Nov 2 <sup>nd</sup> , '21	6.14	4.59	6.25	4.77	0.18 (PBO)	-0.484
Cohort 2 n=214	Nov 3 <sup>rd</sup> , '21 - April 15 <sup>th</sup> '22	6.28	4.98	6.05	4.42	-0.56	0.030

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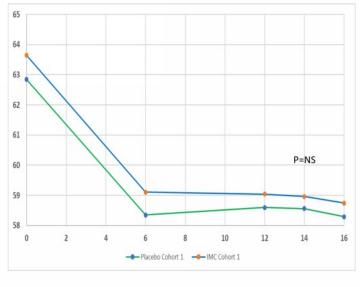
# Primary Efficacy Daily Pain Score By Treatment Week in Cohorts 1 & 2

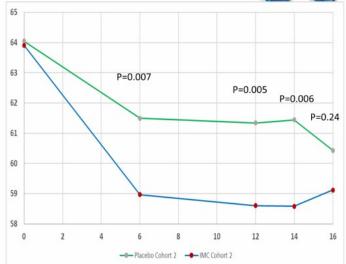




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# PROMIS Fatigue T-Score Improvement By Treatment Week For Cohorts 1 & 2



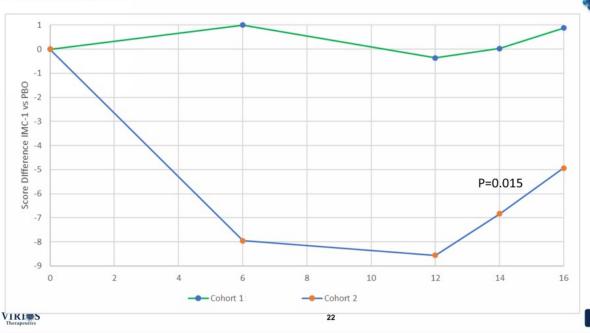


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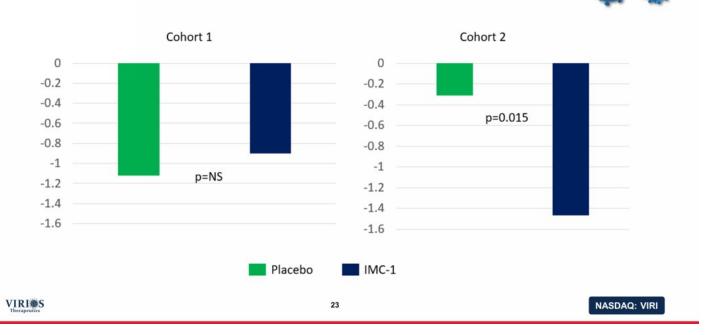
21

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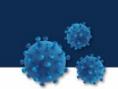
## FIQR Symptom Domain Scores Over 16 Weeks of Treatment: IMC-1 vs. Placebo For Cohorts 1 & 2



## Mean Change in HADS Depression Score by Cohort at Week 14



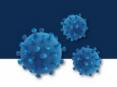
## **FORTRESS Summary**



- Virios management strongly believes this mechanism has potential to improve FM patient care
  - Positive Phase 2a clinical study results
  - IMC-1 in Cohort 2 delivered statistically significant improvement in FM patient pain, fatigue, depression and overall health status
  - IMC-1 in Cohort 2 efficacy results were consistent with the expected profile from previous Phase 2a study
  - The difference in results between Cohort 1 and Cohort 2 is highly unlikely due to chance
- We believe the excellent overall safety and tolerability profile observed in FORTRESS supports future product development
- Our ultimate goal is to get IMC-1 to market
- Our short-term plan is to engage with KOLs/BoD to better understand the Phase 2b data and design a forward development plan to maximize the potential of IMC-1

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### Long Covid Prevalence is Significant



- Approximately 30% of patient infected with the Covid virus will experience post-COVID symptoms — up to six months after recovering
- COVID-19 long-haulers experience an array of widespread and debilitating symptoms even after the virus clears from their system, and latent viruses may account for many symptoms.
- Because of the compromised state of long haulers' bodies, previously dormant viruses are reactivating and becoming chronic infections.
- Neurocognitive impairment and fatigue were linked to serological proof of recent EBV reactivation

120 patients (mean = 111 days post admission)

#### **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%

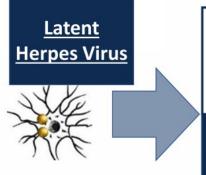
Source: Groff et al, JAMA, Oct 2021; Cox, Gold JE, Okyay RA, et al, Pathogens, 2022; Traylen, Christopher Met al, Future virology, 2011; Bo Diao, Chenhui Wang, et al., 2019



25

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## Potential Link Between Long-COVID and Herpes Virus Reactivation





## **COVID19 Infection**

- ❖ Immune Dysregulation
- Direct Effect on Neurons
- Psychological Stress
- Fever



## **Herpes Reactivation**

- Upregulation of Lytic Genes
- Herpes virus reactivation from latency

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## **Capitalization Table**



Capitalization table as of September 18, 2022

\*Weighted Avg. Exercise Price of \$12.50/share

\*\* Weighted Avg. Exercise Price of \$8.28/share

\*\*\*Includes officers and directors



