



September 27, 2022

Dear Virios (VIRI) Shareholders,

On September 19th, we announced our FORTRESS Phase 2b fibromyalgia (“FM”) study results. In this trial, IMC-1 did not achieve statistically significant improvement on the primary endpoint measure of reduction in FM related pain as compared to placebo. These results were surprising, especially in light of our previously successful Phase 2a study, as well as prior research demonstrating herpes virus activation in patients diagnosed with FM and a functional gastrointestinal disorder.

While these results were not what we had hoped for, we did uncover an anomalous bifurcation of results when comparing the patients enrolled during the first half of the study (“Cohort 1”) with results from patients enrolled during the second half of the study (“Cohort 2”). More specifically, there was no statistically significant differences between treatment with IMC-1 versus placebo for Cohort 1 patients on any of the outcome measures of interest. Conversely, there were statistically significant differences in multiple outcomes of interest including the primary endpoint of reduction in pain at Week 14 as compared to placebo, as well as fatigue and multiple FM related symptoms for those patients in Cohort 2.

The team and I are encouraged by the Cohort 2 results for two reasons. First, these results are consistent with what we expected to see based on the results from our previously completed Phase 2a FM trial. Second, we have statistically modelled the probability that this difference in outcomes between the two cohorts could be a random event, and as a result, the team and I believe that it is highly unlikely that the encouraging Cohort 2 findings could be a random finding.

The team has begun the process of analyzing the FORTRESS data as a whole, as well as by time frame intervals, to determine what might be driving these disparate results and to ascertain what potential options might exist to advance development of IMC-1. This process will take several weeks to complete, following which we anticipate we will likely engage with the FDA to discuss future development options for IMC-1. We expect this process to extend into 2023.

As communicated as recently as our Q2 earnings update in August, our current capital reserves were expected to be depleted at the end of the year. It was within this context that the Board of Directors made a decision to raise additional capital as we explore forward options for IMC-1 development. Without raising additional capital, we would likely not be in a position to determine potential development options for IMC-1, as



raising capital when our cash reserves would on the verge of expiring was deemed to be more dilutive and potentially not achievable.

On an alternative research front, the Bateman Horne Center has been enrolling patients in our exploratory study assessing the therapeutic potential of the combination of valacyclovir and celecoxib to reduce Long-COVID symptoms such as fatigue, sleep, attention, pain, autonomic function and anxiety. We expect to complete enrollment by the end of 2022, with results expected in first half 2023.

In summary, while the FORTRESS Phase 2b FM study results were not what we had hoped for, we are encouraged by the results seen in the Cohort 2 sub-group analysis. As previously communicated, our cash position prior to our recent public offering would have only enabled us to operate through the end of the year. The fresh injection of capital from last week's capital raising was required to create additional runway to properly assess the FORTRESS results with the goal of creating a viable path forward for IMC-1's continued development.

We plan to provide an update on the ongoing analysis at our Q3 earnings update in November. If you have any further questions, please do not hesitate to reach out to me or our SVP of Finance and Corporate Secretary and Treasurer, Angela Walsh at angela@virios.com.

Warmest regards,

Greg Duncan

Greg Duncan
Chair & CEO Virios Therapeutics, Inc.

About Virios Therapeutics

Virios Therapeutics (Nasdaq: VIRI) is a development-stage biotechnology company focused on advancing novel antiviral therapies to treat debilitating chronic diseases, such as [fibromyalgia](#) ("FM"). Immune responses related to the activation of tissue resident herpes have been postulated as a potential root cause triggering and/or sustaining chronic illnesses such as FM, irritable bowel disease, chronic fatigue syndrome and other functional somatic syndromes, all of which are characterized by waxing and waning symptoms with no obvious etiology.



Our lead development candidate, IMC-1, is a novel, proprietary, fixed dose combination of famciclovir and celecoxib designed to synergistically suppress herpes virus replication, with the end goal of reducing virally promoted disease symptoms. The Company is pursuing a second development candidate, IMC-2 (valacyclovir and celecoxib), as a potential treatment for managing the fatigue, sleep, attention, pain, autonomic function and anxiety associated with Long COVID, otherwise known as Post-Acute Sequelae of COVID-19.

For more information, please visit www.virios.com.

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