

Virios Therapeutics Announces First Quarter 2024 Financial Results and Provides Corporate Update

- Top-line results from the ongoing investigator-initiated Bateman Horne Center Long-COVID phase 2 featuring valacyclovir and celecoxib (IMC-2) expected in the second-half of 2024 -

- Conference Call Today at 8:30 a.m. ET -

ATLANTA, May 09, 2024 (GLOBE NEWSWIRE) -- <u>Virios Therapeutics, Inc.</u> (Nasdaq: VIRI) (the "Company"), a development-stage biotechnology company focused on advancing novel antiviral therapies to treat debilitating chronic diseases, including <u>fibromyalgia</u> ("FM") and <u>Long-COVID</u> ("LC"), today announced financial results for the first quarter ended March 31, 2024 and provided a corporate update.

Key Highlights

- The BHC-202 3-arm study comparing two dose levels of the valacyclovir/celecoxib combination vs placebo over 12 weeks to treat symptoms of LC is being conducted by the Bateman Horne Center ("BHC") via an unrestricted investigational grant provided by the Company has surpassed the 50% enrollment level. Top line results are expected in the second-half of 2024.
- Preliminary safety analysis of the BHC-202 study indicates that the combination of valacyclovir and celecoxib ("IMC-2") has been very well tolerated to date with no Serious Adverse Events reported, and only a few transient treatment emergent adverse events being reported.
- Virios' global patent for IMC-2 covering antiviral treatment of LC and Alzheimer's disease has been published. This enables the Company to streamline the process for obtaining patent protection globally, representing a precursor to the national phase of patent examination by targeted countries across the globe.
- Discussions are ongoing as we seek a partner to advance IMC-1 (fixed dosage combination of famciclovir and celecoxib) into Phase 3 development for the treatment of FM.
- The Company continues to actively explore complementary opportunities that will build shareholder value through strategic partnerships, collaborations or other transactions.

"Every week new scientific research highlights the emergence of Long-COVID as a major

unmet medical need, causing significant morbidity amongst children, teenagers and professionals who are unable to attend school or work as a consequence of their Long-COVID symptoms. We are excited to explore our antiviral approach in this crippling condition given the dearth of effective Long-COVID treatment options presently available" said Greg Duncan, Chairman and CEO of Virios Therapeutics. "We believe IMC-2 has the potential to provide a needed treatment option for Long-COVID symptoms and look forward to sharing results from the ongoing BHC study with the research and investor communities later this year."

First Quarter 2024 Financial Results

Research and development expenses for the first quarter of 2024 were \$0.3 million, compared to \$0.5 million for the first quarter of 2023. The quarter over quarter change was due to decreases in expenses for toxicology studies of \$0.1 million and regulatory consulting costs of \$0.1 million.

General and administrative expenses for the first quarter of 2024 were \$1.0 million, compared to \$1.1 million for the first quarter of 2023. The quarter over quarter change was primarily due to a decrease in insurance expenses associated with being a public company.

Net loss for the first quarter of 2024 was \$1.3 million, or \$0.07 basic and diluted net loss per share, compared to a net loss of \$1.5 million, or \$0.08 basic and diluted net loss per share, for the first guarter of 2023.

As of March 31, 2024, Virios Therapeutics' cash totaled \$2.4 million. The Company believes it will have sufficient resources to fund operations into the fourth quarter of 2024.

About Virios Therapeutics

Virios Therapeutics (Nasdaq: VIRI) is a development-stage biotechnology company focused on advancing novel antiviral therapies to treat diseases associated with a viral triggered abnormal immune response such as fibromyalgia ("FM") and Long-COVID ("LC"). Overactive immune response related to activation of tissue resident herpesvirus has been postulated to be a potential root cause of chronic illnesses such as FM, irritable bowel syndrome, LC, chronic fatigue syndrome and functional somatic syndromes, all of which are characterized by a waxing and waning manifestation of disease, often triggered by events which compromise the immune system. Our lead development candidates are novel, proprietary, fixed dose combinations of an antiviral compound and celecoxib designed to synergistically suppress herpesvirus replication, with the end goal of reducing virally promoted disease symptoms. IMC-1 (fixed dosage combination of famciclovir and celecoxib) has been granted fast track designation by the FDA.

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

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Forward-Looking Statements

Statements in this press release contain "forward-looking statements," within the meaning of the U.S. Private Securities Litigation Reform Act of 1995, that are subject to substantial risks and uncertainties. All statements, other than statements of historical fact, contained in this press release are forward-looking statements. Forward-looking statements contained in this press release may be identified by the use of words such as "anticipate," "believe," "contemplate," "could," "estimate," "expect," "intend," "seek," "may," "might," "plan," "potential," "predict," "project," "suggest," "target," "aim," "should," "will," "would," or the negative of these words or other similar expressions, although not all forward-looking statements contain these words. Forward-looking statements are based on Virios Therapeutics' current expectations and are subject to inherent uncertainties, risks and assumptions that are difficult to predict, including risks related to the completion, timing and results of current and future clinical studies relating to Virios Therapeutics' product candidates. 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 Amended Annual Report on Form 10-K/A for the year ended December 31, 2023, filed with the Securities and Exchange Commission. In particular, there can be no assurance that any development partnership or other transaction involving Virios Therapeutics will be completed on favorable terms, or at all. Forward-looking statements contained in this announcement are made as of this date, and Virios Therapeutics, Inc. undertakes no duty to update such information except as required under applicable law.

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-Financial Tables Follow-

VIRIOS THERAPEUTICS Selected Financial Data

(unaudited)

Condensed Statements of Operations Data		March 31,				
	2024		2023			
Revenue	\$	_	\$	_		
Operating expenses:						
Research and development		343,717		497,714		
General and administrative		970,384		1,059,573		
Total operating expenses		1,314,101		1,557,287		
Loss from operations		(1,314,101)		(1,557,287)		
Other income		22,766		40,423		
Net loss	\$	(1,291,335)	\$	(1,516,864)		
Net loss per share of common stock — basic and diluted	\$	(0.07)	\$	(0.08)		
Weighted average shares outstanding — basic and diluted	<u></u>	19 257 937		18 330 390		

Three Months Ended

Condensed Balance Sheet Data		March 31, 2024		December 31, 2023	
Cash	\$	2,379,532	\$	3,316,946	
Total assets		3,224,611		4,165,442	
Total liabilities		570,083		358,548	
Total stockholders' equity		2,654,528		3,806,894	

Source: Virios Therapeutics, Inc.



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