

Virax Biolabs Completes UK Clinical Recruitment and Reports Constructive FDA Feedback for ViraxImmune™ Study Evaluating T Cell Dysfunction in Post-Acute Infection Syndromes

LONDON, Nov. 3, 2025 /PRNewswire/ -- Virax Biolabs Group Limited (NASDAQ: VRAX) ("Virax" or the "Company"), an innovative biotechnology company focused on the detection of immune responses to and diagnosis of viral diseases, today announced that it has successfully completed patient recruitment for its United Kingdom-based, multi-centre clinical study evaluating the performance of the ViraxImmune™ assay in detecting T cell dysfunction in Post-Acute Infection Syndromes ("PAIS"), including Long COVID, post-treatment Lyme disease ("PTLD"), and Myalgic Encephalomyelitis / Chronic Fatigue Syndrome ("ME/CFS").



The study, conducted in collaboration with the UK's National Health Service ("NHS"), has achieved full enrolment ahead of schedule, reaching its target of 160 participants. It was randomised in a 3:1 ratio between symptomatic and non-symptomatic participants, with 40 patients recruited for each of the three symptomatic cohorts representing Long COVID, PTLD, and ME/CFS. The trial is designed to evaluate T cell dysfunction and immune dysregulation underlying the major symptoms observed in PAIS.

The collected clinical samples will now undergo immunological analysis to evaluate the performance of the ViraxImmune™ assay in detecting T cell dysfunction as an aid in diagnosing PAIS in patients experiencing persistent and debilitating fatigue. The results from this analysis are intended to support regulatory submissions in the United Kingdom, including filings with the Medicines and Healthcare products Regulatory Agency ("MHRA"), and may also inform subsequent U.S. submissions.

"It was hugely encouraging to see so many patients from across the country keen to contribute to this important research," said Dr James Shepherd, Consultant in Microbiology and Infectious Diseases at NHS Greater Glasgow and Clyde and Honorary Clinical Senior Lecturer at the MRC-University of Glasgow Centre for Virus Research, who serves as the study's Principal Investigator. "There is enormous demand for improved understanding and diagnostic tools for post-acute infection syndromes. The ViraxImmune™ platform represents an exciting step forward in the scientific and clinical approach to these complex immune conditions."

In parallel, Virax announced that it received final minutes from its productive pre-submission

meeting with the U.S. Food and Drug Administration ("FDA") on September 10, 2025, to discuss the proposed regulatory pathway for its ViraxImmune™ T cell assay. The meeting provided constructive feedback on the Company's continued development of the assay for use in patients with post-acute COVID-19 infection. Virax is incorporating the Agency's recommendations into its ongoing clinical and analytical development programs to support progress toward a future submission in the United States. The Company anticipates commencing its U.S.-based clinical study in 2026 in partnership with Emory University.

James Foster, Chief Executive Officer of Virax Biolabs, added:

"Completing full UK clinical recruitment ahead of schedule, alongside receiving constructive FDA feedback, represents an important dual milestone for ViraxImmune™. Together, these achievements strengthen our global regulatory position and advance our goal of enabling T cell-based immune profiling to improve diagnosis and management of post-acute infection syndromes."

Initial read-outs from this longitudinal study are expected in Q2 2026.

About Virax Biolabs Group Limited


Virax Biolabs Group Limited is an innovative biotechnology company focused on the detection of immune responses to and diagnosis of viral diseases. Virax Biolabs Group Limited is developing T cell-based test technologies with the intention of providing an immunology profiling platform. T cell testing can be particularly effective in the diagnosis and therapeutics of post-acute infection syndromes such as Long COVID and other chronic conditions linked to immune dysregulation.

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

Caution Concerning Forward-Looking Statements

This press release contains forward-looking statements. In addition, from time to time, we or our representatives may make forward-looking statements orally or in writing. We base these forward-looking statements on our expectations and projections about future events, which we derive from the information currently available to us. Such forward-looking statements relate to future events or our future performance, including: our financial performance and projections; our growth in revenue and earnings; and our business prospects and opportunities. You can identify forward-looking statements by those that are not historical in nature, particularly those that use terminology such as "may," "should," "expects," "anticipates," "contemplates," "estimates," "believes," "plans," "projected," "predicts," "potential," or "hopes" or the negative of these or similar terms. In evaluating these forward-looking statements, you should consider various factors, including: our ability to change the direction of the Company; our ability to keep pace with new technology and changing market needs; and the competitive environment of our business. These and other factors may cause our actual results to differ materially from any forward-looking statement. Forward-looking statements are only predictions. The forward-looking events discussed in this press release and other statements made from time to time by us or our representatives may not occur, and actual events and results may differ materially and are subject to risks, uncertainties, and assumptions about us. These forward-looking statements are based on information currently available to Virax and its current plans or expectations and are subject

to a number of known and unknown uncertainties, risks 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. These and other important factors are described in detail in the "Risk Factors" section of Virax's Annual Report on Form 20-F for the year ended March 31, 2025. 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. We are not obligated to publicly update or revise any forward-looking statement, whether as a result of uncertainties and assumptions, the forward-looking events discussed in this press release and other statements made from time to time by us or our representatives might not occur.

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