December 17, 2024

Virax Biolabs' CEO James Foster Issues Letter to Shareholders

LONDON, Dec. 17, 2024 /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 Mr. James Foster, Chief Executive Officer of Virax, has issued a letter to shareholders outlining the Company's plans for 2025 and highlights recent accomplishments.

Dear Fellow Shareholders,

As we wrap up 2024 and look forward to the year ahead, we are excited to share an update on our achievements and outline our strategic goals for 2025. Over the past year, we have enhanced our capabilities, forging new and expanding existing distribution partnerships, and deepened our commitment to addressing indications associated with chronic inflammation and immune dysfunction.

Our goal at Virax is to bring to the market a comprehensive set of T-cell diagnostics and immune profiling solutions utilizing our novel **ViraxImmune™ in vitro diagnostic (IVD)** platform. Our broad strategic focus is to develop and commercialize immune profiling in vitro diagnostics in post-acute infection syndromes and protective immunity. This year we have launched **ImmuneSelect**, our research-use-only version of ViraxImmune™, which includes immune profiling assays targeting researchers, clinicians and drug developers working in the areas of chronic inflammation and immune dysfunction. Additionally, our **ViraxClear** portfolio offers a diverse selection of PCR and antigen-based test kits designed to target various pathogens to support public health initiatives and disease control.

These distinct diagnostic solutions exemplify our commitment to advancing global health through innovative testing platforms, establishing a strong foundation for the significant strides we anticipate in 2025.

Major Developments in 2024

We have spent the past year making improvements to our laboratory facility which we believe to be fully staffed and equipped for the next stage of our development process.

We are pleased to announce the initiation of a clinical study in the United Kingdom (NCT06731179) aimed at assessing the ViraxImmune™ platform's performance in detecting T-cell dysfunction in post-acute infectious syndrome patients, including those with long COVID, post-treatment Lyme disease (PTLD), and Myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS). The study will enroll up to 160 participants, with first patient

dosed anticipated in early Q1 2025, followed by initial data readout anticipated in Q1 2026.

Building on the progress of initiating our UK-based clinical validation study, we are also focusing on advancing our U.S. regulatory and clinical development. To facilitate this, we have begun discussions with renowned U.S. based clinical institutions to initiate studies to support our IVD development. Additionally, activities have been initiated to submit a request for a formal meeting with the FDA through its pre-submission program, also known as Q-submission. This will allow us to receive formal written feedback from the FDA regarding our ViraxImmune™ IVD clinical development and regulatory plans in the U.S., including guidance on our clinical validation and performance testing. We anticipate receiving the FDA written feedback by Q2 of 2025, followed by the initiation of our U.S. based clinical validation study.

In addition, as part of our launch and commercialization plans for our ViraxImmune™ IVD platform, we aim to establish strategic collaborations with CLIA laboratories in the U.S. to offer laboratory development tests (LDTs) for clinical studies to support the development of our ViraxImmune™ platform. We have initiated consulting activities in the U.S. with external partners to assist with market research and pricing activities needed for product placement of this launch.

Alongside advancing the ViraxImmune™ IVD platform, we launched our research-use-only (RUO) ImmuneSelect portfolio in Q2 of 2024. ImmuneSelect is a commercially available suite of research-use-only (RUO) immune profiling solutions, including peptide pools, ELISpot kits, and recombinant antibodies. This enables researchers and drug developers to study T-cell activation, immune profiling, and immune status in infections and conditions linked to chronic inflammation and adaptive immune dysfunction.

New Distribution Agreements

Building on the commercial launch of our ImmuneSelect portfolio, we are expanding our global distribution infrastructure. This year, we reached agreements with regional distributors Europa Biosite and Tebubio to distribute ImmuneSelect products across the European Union, as well as the UK, Norway, and Switzerland; increasing access for researchers and pharmaceutical entities in that region. In addition, we have signed country specific distribution agreements for ImmuneSelect in Spain and Portugal with Abyntek Biopharma, and in Italy with DBA Italia. To expand access further, we aim to secure U.S. distribution partners by Q1 of 2025.

These developments have been supplemented by the continued expansion of our ViraxClear distribution channels. We entered into a new agreement to supply Mpox Virus Real-Time PCR Detection Kits to 13 European countries and the Middle East. We also expanded our current agreement with Cosmos Health to extend the distribution of the Mpox Virus Real-Time PCR Detection Kits to countries in the Gulf Cooperation Council (GCC) and India. In addition, ViraxClear maintains the capability to distribute H5N1 testing kits, commonly known as Avian Flu tests, and can ship them as needed.

Looking Ahead to 2025

In 2025, our key priorities include:

- Advancing ViraxImmune™ UK and U.S. Clinical Validation Studies: We will be leveraging insights gained from ongoing data and collaborations to fine-tune our offerings for broad-scale deployment. We expect to present key data at major international scientific conferences.
- U.S. regulatory Progress: We aim to initiate formal interactions with regulatory authorities to define the approval pathway for the ViraxImmune™ IVD platform. This step is critical to transitioning our innovative assays into clinical use.
- Expansion of ImmuneSelect Distribution Channels: Building on recent agreements, we will focus on growing our presence in additional markets, with particular emphasis on the Americas, and into U.S.-based markets.
- Initiation of Protective Immunity IVD clinical performance study (Lyme Disease and Pre & Post Transplant Infection).

This multi-faceted approach underscores our commitment to innovation, market growth, and scientific excellence as we position Virax as a leader in immune diagnostic solutions.

Financial Highlights

Research and development activities have accelerated from the prior year in both capital expenditures and research expenses. We have tripled our laboratory area since signing our first lease in BioCity, Glasgow in August 2023 and doubled our property, plant and equipment for that lab to approximately $1.1 million as of September 30, 2024 from the prior period. Our ongoing research and development expenses were approximately 33% higher year over year as of September 30, 2024.

During 2024, we received approximately $0.8 million from a warrant exercise and approximately $5.1 million from two cash for stock transactions, each in increasing valuation per raise. Our cash balance as of September 30, 2024 was approximately $7.3 million and working capital was approximately $6.6 million. In addition, we do not have any long-term debt obligations. Regarding the stock valuation, as of December 10, 2024, our shares are trading at a price less than our current cash on hand per share. We believe this valuation is not representative of the overall value and future potential of Virax. With the current cash balance and no debt to service, we believe we have adequate capital to fund our near-term priorities.

Commitment to Innovation and Impact

The challenges posed by post-acute infection syndromes such as long COVID underscore the urgent need for new diagnostic tools, and we are proud to be at the forefront of addressing this global issue. In the next 12 months, we eagerly anticipate substantial advancements in the development of our ViraxImmune™ platform and expanding our distribution footprint to the U.S. and other regions.

We are deeply grateful for your continued support as we work to advance our mission and deliver value to our shareholders, partners, and the broader medical community.

Sincerely,

James Foster
Chairman and CEO

Virax Biolabs Group Limited

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 currently 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-viral 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, 2024. 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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