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# VGI Health Technology Limited

**Sydney New South Wales**, **19 October 2022** – The Directors of VGI Health Technology Limited (the **Company** or **VTL**) are pleased to provide the following update for the quarter ending 30 September 2022.

## **Status of Patent Ownership**

There were no material developments in relation to the Company's patents during this period.

## **Technological and Product Development**

On 5 July 2022, the Company was pleased to announce that its wholly owned subsidiary, Invictus Ops Pty Ltd (Invictus), had commenced recruitment of patients for its Phase II clinical study in Non-Alcoholic Fatty Liver Disease (NAFLD)/Non-Alcoholic SteatoHepatitis (NASH). The study will enrol eighty patients across eight sites in Australia, with two sites The Gallipoli Medical Research Foundation (GMRF) in Queensland and The Royal Melbourne Hospital in Victoria now commencing recruitment of patients. This study will be a randomised, double-blind, placebo-controlled Phase II clinical study on NAFLD/NASH to analyse the efficacy and safety of IVB001, a drug candidate based on the non-invasive and direct delivery of tocotrienols using Invictus' patented transmucosal delivery platform.

On 14 September 2022, the Company was pleased to announce that its wholly owned subsidiary, Invictus Ops Pty Ltd (Invictus), had made significant progress in its Phase II clinical study in Non-Alcoholic Fatty Liver Disease (NAFLD)/Non-Alcoholic SteatoHepatitis (NASH). Research Governance Office approvals have been received from the Fiona Stanley Hospital in Western Australia, the Concord Repatriation General Hospital and the John Hunter Hospital in New South Wales and these sites have been added as clinical study sites along with the existing sites The Gallipoli Medical Research Foundation (GMRF) in Queensland and The Royal Melbourne Hospital in Victoria. The GMRF had recruited the first patient for this clinical study.

On 26 September 2022, the Company was pleased to announce that its wholly owned subsidiary, Invictus Ops Pty Ltd (Invictus), had received ethics approval to proceed with a US pharmacokinetics and exercise clinical study. Institutional Review Board (IRB) approval was received by Invictus' research partner, Altipure R&D in Ohio, USA, to conduct a clinical study comprising 45 healthy volunteers to assess the bioavailability of delta tocotrienols (DT3) which have been administered via Invictus' transmucosal delivery platform. The study will also measure exercise performance and muscle power for two doses of Invictus' exercise performance nutraceutical product NE1-Elite® along with other endpoints such as lactate, glucose and lipids in the blood. Changes in muscle and fat mass will also be measured. This study will open up a great opportunity for new products both in the Company's nutraceuticals and pharmaceuticals pipeline.

On 5 October 2022, the Company was pleased to announce that its wholly owned subsidiary, Invictus Ops Pty Ltd (Invictus), had commenced dosing of patients for its Phase II clinical study in Non-Alcoholic Fatty Liver Disease (NAFLD)/Non-Alcoholic SteatoHepatitis (NASH). Dosing of Invictus' NAFLD/NASH drug candidate IVB001 has commenced for 1 patient at The Gallipoli Medical



Research Foundation in Queensland and 3 patients at The John Hunter Hospital in New South Wales. A total of 80 patients will be recruited and dosed for this study which is a randomised, double-blind, placebo-controlled Phase II clinical study on NAFLD/NASH to analyse the efficacy and safety of IVB001, a drug candidate based on the non-invasive and direct delivery of tocotrienols using Invictus' patented transmucosal delivery platform. Dr David Kingston, the Chief Scientific Officer of VTL, said "Unlike many other Phase II clinical studies, the present study is based on efficacy signals derived from clinical studies on orally administered tocotrienols rather than animal studies and we have seen some promising results in NAFLD/NASH patients who have been administered a dietary supplement which is closely aligned to the drug candidate IVB001. This study is showing a lot of promise and we hope to be able to address the great unmet need presented by NAFLD/NASH."

#### **Customer Recruitment**

There were no material developments in the recruitment of customers for the Company's nutraceuticals business during the quarter.

## **Quarterly Revenue**

An update on the revenue for the March quarter will be provided in the NSX quarterly update to be released to the Market before the end of October.

#### **Staff Recruitment**

No new staff were recruited during the quarter.

For more information please contact:

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### About VGI Health Technology Limited

VGI Health Technology Limited trading as VGI Health Technology is an Australian public listed company (NSX:VTL). VTL refers to recent announcements about the divestment of its wholly owned subsidiary Invictus BioPharma Pty Ltd. Post completion of this transaction, VTL will be focussed on manufacturing, marketing and selling novel dietary supplements based on natural products (tocotrienols) which have wide therapeutic potential, including: Delayed Onset Muscle Soreness, muscle recovery and exercise endurance. The Company has a product development program for evidence-based nutraceuticals.

For more information see: <a href="https://www.vgiht.com">https://www.vgiht.com</a>

Investors interested in trading shares on the NSX should contact a broker who is an NSX Participant: <a href="https://www.nsx.com.au/broker\_list\_print.asp">https://www.nsx.com.au/broker\_list\_print.asp</a>