



Contract Research Organisation Appointment

Melbourne, Australia, December 22nd, 2022 – InhaleRx Ltd (ASX: IRX), (**InhaleRx**’ or **‘the Company**’) an Australian healthcare company developing unique medicinal cannabinoid drug-device products to address unmet medical needs in pain management and mental health sectors, is pleased to announce that it intends to appoint Ingenu CRO Pty Ltd (**‘Ingenu**’) as Contract Research Organisation (**‘CRO**’) for the Company’s planned Complex Regional Pain Syndrome (**‘CRPS**’) and Panic Disorder (**‘PD**’) clinical trials.

InhaleRx’s Chairman, Mr Sean Williams said; “Following a comprehensive tender process, I am pleased to advise that the Company has selected Ingenu as its CRO partner for its planned CRPS and PD clinical trial programmes. Ingenu was selected on the basis of its capability and experience as a specialist cannabinoid CRO, which enabled it to develop and present an attractive tailored, time efficient and cost-effective approach to IRX’s clinical trial requirements. This approach also, very importantly, allowed Ingenu to present an offer to IRX which was substantially more attractive on a value for money basis than other tendered offers. We look forward to working closely with Ingenu over the next 12-18 months as we complete our planned Phase 1 and 2 clinical trials for CRPS and Phase 2 PD clinical trials.”

InhaleRx’s CRO tender process included the involvement of six local, regional (Asia-Pacific) and international CRO businesses. The tender was run by a committee comprising of IRX’s non-executive directors Mr Williams and Dr Andrew Saich. Mr Ron Budhram, a UK based clinical trial specialist with over 30 years experience, was also invited to join the Committee as a subject matter expert.

The consideration payable by the Company to the CRO for the planned CRPS and PD clinical trials is \$5m to be paid in cash.

Ingenu is considered a related party of the Company as InhaleRx’s CEO and former director, Mr Darryl Davies, is also the Chief Operating Officer and a director of Ingenu. Ingenu is also a subsidiary company of substantial InhaleRx shareholder, Cannvalate Pty Ltd. As such, the appointment of Ingenu as CRO is subject to shareholder approval for the purposes of ASX Listing Rule 10.1. An Extraordinary General Meeting of the Company will be scheduled in the new year for this purpose. Neither Mr Davies nor Cannvalate Pty Ltd will be entitled to vote on the resolution.

The Company has engaged Hall Chadwick to complete an Independent Expert’s Report (**‘IER**’) for the purpose of seeking shareholder approval to appoint Ingenu for the purposes of ASX Listing Rule 10.1. A copy of the IER will be provided with the Notice of Meeting and Explanatory Memorandum.

InhaleRx’s Chief Scientific Officer, Dr Rob Jenny said; “We are very excited to be working with the Ingenu CRO team, which is highly experienced and regarded as world leaders in conducting cannabinoid and psychedelic clinical trials. We look forward to commencing the clinical trial program in Melbourne in the new year having finalised the required Protocols, Investigator’s Brochures and trial drug-device formulations over the course of recent months.”

Authorised by the Board of Directors.

For further information:

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About InhaleRx Limited (ASX: IRX) – www.inhalerx.com.au

InhaleRx Limited (ASX: IRX) (“InhaleRx” or “the Company”) is an Australian healthcare company which is developing novel cannabinoid derived drug device combination medications to serve unmet needs in pain management and mental health sectors.

The overarching goal is to pursue U.S. FDA approval and registration to treat Panic Disorder and Complex Regional Pain Syndrome using rapid and cost effective regulatory pathways, such as 505(b)(2). A 505(b)(2) application is a New Drug Approval (NDA) that contains full reports of investigations of safety and effectiveness, where at least some of the information required for approval comes from studies available in the public domain.

There is a significant economic opportunity for InhaleRx and the Company’s shareholders as these carefully selected medical indications under investigation currently have extremely limited treatment options, whilst also offering a low side effect profile.

InhaleRx holds an innovation patent and will be developing further defensible IP as the two clinical trial programmes enter the execution phase.