



17 February 2023

ASX Announcement

Chairman's address to EGM

Before we turn to consideration of the formal meeting resolutions – which are the purpose of the meeting, I would like to provide some contextual background on the importance of these resolutions.

InhaleRx Ltd (ASX: IRX), ('InhaleRx', 'IRX' or 'the Company') is presently a small company, both by market capitalisation and the scale of its operations, but significant ground was covered by the small, but extremely capable IRX team over the course of 2022 calendar year. Our CEO, Mr Darryl Davies, will provide you with a more comprehensive up-date of these developments after the formal business of the meeting have been completed.

I would like, however, to highlight the important progress made during the year with respect to the Company's novel treatments for Complex Regional Pain Syndrome (CRPS) and Panic Disorder (PD).

In the case of each treatment, IRX has now completed the following:

- Development of novel drug formulations and the completion of stability testing;
- Drafting of clinical trial Protocols and Investigator Brochures;
- Identified and procured the necessary Active Pharmaceutical Ingredients (API) and pressurised metered dose inhaler (pMDI) device componentry;
- Commissioned the manufacturing of the trial drugs; and
- Completed an international tender for the selection of a Clinical Research Organisation (CRO) to oversee the clinical trial programmes.

In addition, the IRX team has also continued to make significant progress in the Company's journey towards opening an Investigational New Drug (IND) application with the US Food & Drug Administration (FDA) for each indication. Significantly, IRX has completed a pre-IND meeting with the FDA covering its plans for the development of its Cannabidiol (CBD) drug device combination for the treatment of PD – which was a very informative and affirming meeting. IRX has also progressed an Ethics Committee submission in preparation for the planned Phase 1 clinical trial of its Tetrahydrocannabinol (THC) based drug-device combination for the treatment of CRPS to be conducted here in Melbourne over the coming months. A pre-IND meeting with the FDA for this treatment has also been scheduled for 30th March 2023.

The next steps in the clinical pathway for each indication is reliant on IRX shareholders approving Resolution 1, which authorises the appointment of Ingenu CRO Pty Ltd (which is a related party) as CRO for the proposed clinical trial programme for each. Ingenu CRO was selected through a competitive tender process and also presented the most attractive offer received on a value for money basis.

The planned clinical trial programme will be some of the first clinical trials involving inhaled cannabinoid medications for treating pain and anxiety related conditions. Furthermore, we expect that they will also be the first clinical trials for inhaled cannabinoid treatments for CRPS and panic disorder to be completed anywhere in the world. The IRX board and management team are very excited about the prospect of getting the clinical trial programmes underway and are very optimistic about where these programmes may lead.

IRX's progress across 2022 was supported by the capital raise of \$1.2m in September 2022 which enabled the Company to complete its drug formulation work, procurement and trial drug manufacturing priorities.

Resolutions 2 and 4 are related to the approval of the costs of this capital raise and the involvement of a major shareholder (which is also a related party), Cannvalate Pty Ltd, in supporting that capital raise. Resolution 3 will allow the Company the necessary flexibility to continue to raise capital as required over the next 12 months in order to fund the proposed clinical trial programme.

Sean Williams
Chairman

Authorised by the Board of Directors.

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

InhaleRx Limited is an Australian healthcare and technology company which is focused on developing inhalation therapies. The Company currently markets the Medihale inhalation device and is working on developing a range of inhaled therapeutic medicinal formulations for registration domestically and internationally.