ASX Announcement

QUARTERLY ACTIVITIES, CASHFLOW REPORT and OPERATIONS UPDATE

Quarter ended 30 June 2022

InhaleRx Ltd (ASX:IRX) ("IRX" or the "Company") is pleased to provide its quarterly activities, cash flow report and an update of operations.

Operational highlights are as follows:

- Cash reserves at 30th June 2022: $1,893k
- Net cash used in the quarter for operating activities: ($608k)
- Panic Disorder (**PD**) drug formulation work completed, initial stability results are very promising and additional stability testing underway.
- Complex Regional Pain Syndrome (**CRPS**) drug formulation work underway and expected to be completed shortly before going onto stability testing.
- Technical transfer to commence trial batch manufacturing is on track and scheduled for the coming months.
- White label sales of Medihale™ continue and the Company has experimented with other delivery devices to acquire market insights and information from the medical community device preferences.

The net cash outflow from operating activities during the quarter was $608k, with the company commencing its investment in drug formulations for Complex Regional Pain Syndrome (**CRPS**) and Panic Disorder (**PD**) ahead of commencement of clinical trials. The Company continues to apply a disciplined approach to the incurrence of operational expenditure.

Clinical development pathway - general up-date

The Company's core focus for the June 2022 quarter has been on the development of drug formulations for use in its clinical programme as part of its development of inhaled cannabinoid formulations for the treatment of CRPS and PD.

The overarching goal is to achieve a New Drug Approval (**NDA**) with the US Food & Drug Administration (**FDA)** . IRX is committed to driving cost efficiencies while delivering outcomes in the shortest time frame possible.

The Company has assembled a world class team to further refine the trial design across the two programmes so it can successfully execute on this strategy.

Formulation: IRX is working closely with a UK-based drug formulation specialist tasked with the development of medications to be dispensed via pressurized metered dose inhalers (**pMDI**) for the treatment of CRPS and PD.

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Manufacturing: Three contract manufacturing options have been short-listed for the purpose of supplying the drug -pMDI's combinations required for both clinical trials. Two have made it through the due diligence process and it is anticipated that the IRX Board will make a decision in the coming weeks on the successful manufacturer.

Contract Research Organisation (CRO): Delays in the commencement of the THC formulation work have resulted in IRX postponing the commencement of a tender process for selection of a CRO. However the tender documents have now been prepared and will shortly be issued to a short-listed selection of CROs.

The Panic Disorder (PD) opportunity

The sudden onset of panic attacks can currently not be managed satisfactorily.

Prevalence:

6.97m American Adults suffering with Panic Disorder, which is an estimated **2.7% of U.S. adults**[3]

TAM:

USA: approx. **USD 45.15b**[4] *(based on prevalence x annualised cost of medical costs)*

Existing Drugs:

Antidepressants (SSRI), benzodiazepines, gabapentin, and mirtazapine help to reduce frequency of attacks.

Pathway:

FDA 505(b)(2)

PD clinical trial programme update

Drug-Device: IRX has completed initial formulation work, with solubility and spray characteristics now determined. Stability testing is currently underway and the results obtained so far from the 1-month time point are very encouraging. Results from the 3-month time point are expected in early September 2022. The individual pMDI device componentry has been determined and compatibility with the drug substance at the 1-month stability time point is performing as expected.

Clinical Trial: Preparations for the commencement of the Phase 2 (proof-of-concept) trial are on track with the first patient in anticipated to be between Feb-April 2023. The investigator's brochure (**IB**) has been drafted and the clinical trial protocol is in the final stages of completion.

Regulatory: IRX has continued to work with Premier Consulting (formerly known as Camargo Pharmaceutical Services) towards a NDA with the FDA. Premier Consulting has performed a detailed regulatory assessment of IRX's drug-device candidate and it is expected that a pre-Investigational New Drug (**Pre-IND**) meeting with the FDA will be held in the June half of 2023. An Investigational New Drug (**IND**) number has been recently issued to IRX by the FDA in anticipation

of this meeting (163026).

Complex Regional Pain Syndrome (CRPS) opportunity

The sudden onset of pain and time to analgesic effect from current treatments is mismatched.

Prevalence:

219,317[1] cases in the United States, the total (2017) - *Confirmed Orphan Status*

TAM:

USA: approx. **USD 7.08b**[2] *(calculated by the prevalence x the average rebate under ODD)*

Existing Drugs:

No drugs have been specifically approved for CRPS.

Patients resort to combination of opioids/lyrica and atypical antidepressants.

Pathway:

FDA 505(b)(2) + Orphan Drug Designation (ODD)

CRPS clinical trial programme

Drug-Device: Following unexpected delays in the importation of the active pharmaceutical ingredient (API) from the US to the UK, the process of formulating the drug solution for the CRPS pMDI was unable to commence until late June. Nevertheless, rapid progress has been made with confirming the target dosage and solubility potential of the base formulation. An initial stability matrix is underway with results from the 1-month time point expected in early August. Selection of the individual pMDI device componentry has been shortlisted with performance at the 1-month stability time point expected to be instructive.

Clinical Trials: Preparations for the commencement of the Phase 1 and Phase 2 (proof-of-concept) trials are on track with the First Patient In (FPI) anticipated to be between June-August 2023. The clinical trial protocol has been drafted and the IB is awaiting confirmation of the drug formulation prior to being finalised.

Regulatory: IRX's application has undergone a detailed regulatory assessment by Premier Consulting and information has been prepared to support an identified target date for a CRPS Pre-IND meeting with the FDA.

An Orphan Drug Designation (**ODD**) has been filed with the FDA for CRPS. IRX has received a response from the FDA to this initial application and the Company is now working through collating the next layer of data in support of this application. IRX anticipates re-filing with the FDA once the necessary data is obtained through the upcoming Phase 2 trial.

Licences

IRX has been granted a wholesale licence by the Victorian Department of Health & Human Services under the Drugs, Poisons and Controlled Substances Act 1981 which allows it to store and distribute scheduled substances, including all Schedule 2, 3, and 4 medications, as well as, limited Schedule 8 medications (which includes medicinal cannabis).

The Company has also now applied for import/export licences with the Office of Drug Control (ODD) to enable it to procure the necessary medicinal cannabinoid medications offshore for use in the forthcoming clinical trial programmes, and we expect this to be granted shortly.

White label opportunities for Medihale

IRX continues to develop its Medihale vape device offering and is in the process of trialing another vape device to better understand the advantages and shortfalls of popular existing delivery systems.

The Company's 'white label' offer continues to gather momentum with a number of parties showing interest across the Australian and New Zealand markets.

Payments to Directors & Related Parties

Cash payments to Directors during the quarter totaled $51k.

Use of funds

During the quarter, funds spent on operating activities comprised:

- $223k in clinical development costs (including medical writing and drug formulation costs);
- $173k in annual insurance premiums;
- $67k in legal, tax and audit related costs;
- $51k in director fees (including executive director fees);
- $11k for sales and marketing;
- $83k in general corporate costs including consultants ($37k) and German subsidiary winding-up costs ($12k).

The Company will provide further updates in due course.

Authorised by the Board of Directors.

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References

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3. *https://adaa.org/understanding-anxiety/facts-statistics*
4. *https://pubmed.ncbi.nlm.nih.gov/16075454/*

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