29 April 2022

ASX Announcement

QUARTERLY ACTIVITIES, CASHFLOW REPORT and OPERATIONS UPDATE

Quarter ended 31 March 2022

InhaleRx Ltd (ASX:IRX) ("InhaleRx" 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 31st March 2022: $2,501k
- Net cash used in the quarter for operating activities: ($305k)
- Panic Disorder (**PD**) drug formulation work commenced and now nearing completion
- Appointment of Key Opinion Leader (**KOL**) for proposed PD clinical trials
- Licence to supply/wholesale-controlled substances granted to IRX
- White label opportunities for Medihale continue to build.

The net cash outflow from operating activities during the quarter was $305k, with the company continuing to streamline its operations and adopt a disciplined approach to the incurrence of operational expenditure.

Clinical development pathway up-date

The Company's core focus for the March 2022 quarter has been on the implementation of its clinical programme for the development of inhaled cannabinoid formulations for the treatment of Complex Regional Pain Syndrome (**CRPS**) and Panic Disorder (**PD**).

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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)*

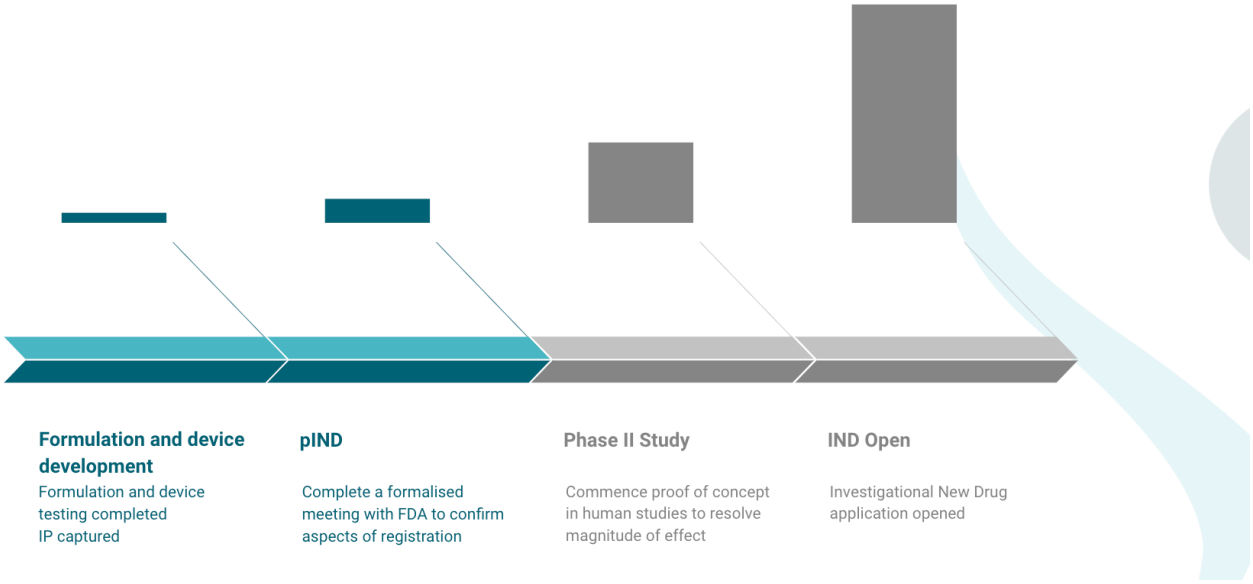
Existing Drugs:

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

Pathway:

FDA 505(b)(2)

The overarching goal is to have the formulations approved as a treatment for these conditions by the FDA (USA).



IRX has engaged Premier Consulting (formerly known as Camargo Pharmaceutical Services) to complete an initial feasibility and regulatory assessment on its preferred pressurized metered dose inhaler (**pMDI**) to confirm suitability for use in IRX's Pre-IND application to the FDA for CRPS and PD.

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Information has been prepared to support an identified target date for the CRPS Pre-IND meeting, and the PD preparation work is still ongoing.

IRX has recently engaged a specialised UK based drug formulation provider to assist in the development of inhaled drug formulations for the treatment of CRPS and PD via a pressurized metered dose inhaler (**pMDI**). The CBD based PD formulation has progressed quickly and is currently completing testing for optimal dosing, with stability testing to follow.

Requirements for export licences with the US Drug Enforcement Agency (**DEA**) relevant to the sourcing of the THC derived Active Pharmaceutical Ingredient (**API**) have caused a longer than expected delay in the commencement of the CRPS formulation process. It is currently expected that this work will commence in June once the API is received in the UK.

IRX has recently appointed Professor Philip Boyce as Key Opinion Leader (**KOL**) for its clinical trial investigations for PD. Professor Boyce has a long clinical and research interest in anxiety disorders, mood disorders, psychosomatic disorders, and perinatal psychiatry. He is a Professor of Psychiatry and Head of Discipline of Psychiatry at the University of Sydney, and Head of the Perinatal Psychiatry Clinical Research Unit at Westmead Hospital. Professor Boyce has published more than 170 articles, and frequently contributes to psychiatric textbooks and currently also serves as associate editor of *Australian and New Zealand Journal of Psychiatry*.

During the March quarter, IRX engaged two highly experienced independent contractors for medical writing and biostatistical /pharmacokinetic services for the purposes of drafting the clinical trial synopses and The Investigators Brochures (**IB**) for the PD and CRPS clinical trials. This work is now complete for the PD indication and is nearing completion for CRPS, pending finalisation of the drug formulation work (as outlined above).

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 the application.

The delay in formulation works for the CRPS drug has caused IRX to pause its clinical research organisation (CRO) tender process, with the tender documentation to be issued immediately once the IB for CRPS is finalised.

The Company has short-listed a number of contract manufacturing partners for the supply of the cannabinoid formulation-pMDI combinations for use in the clinical trials and is in the process of developing final recommendations for board approval.

IRX was recently 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 (ODC) to enable it to procure the

necessary medicinal cannabinoid medications offshore for use in the forthcoming clinical trial programmes.

White label opportunities for Medihale

IRX continues to develop its Medihale vape device offering and is in the process of trialing another pod size to further refine the product. Testing is also underway for the use of E-nicotine with the Medihale device for treating patients seeking support in smoking cessation.

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 $85k.

Use of funds

During the quarter, funds spent on operating activities comprised:

- $113k in clinical development costs (including medical writing and drug formulation costs);
- $85k in director fees (including executive director fees);
- $31k in legal, tax and audit related costs;
- $6k for sales and marketing; and
- $70k in general corporate costs including consultants ($25k) and PAYG tax payments ($16k).

The Company will provide further updates in due course.

Authorised by the Board of Directors.

For further information:
www.inhalerx.com.au

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References

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2. *https://rarediseases.org/wp-content/uploads/2021/03/orphan-drugs-in-the-united-states-NRD-2020.pdf*
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