ASX Announcement

QUARTERLY ACTIVITIES, CASHFLOW REPORT and OPERATIONS UPDATE

Quarter ended 30 September 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 September 2022: $1,937k
- Net cash used in the quarter for operating activities: ($371k)
- Appointment of Dr John Crock as a non-executive director, Mr Darryl Davies as Chief Executive Officer and Dr Rob Jenny as Chief Scientific Officer.
- $1.2m Share Placement completed on 3rd October 2022 with 17,500,000 fully paid ordinary shares in the Company issued at a price of $0.06 (6 cents) per share. A further 2,500,000 Shares will be issued pursuant to the Share Placement following shareholder approval.
- Panic Disorder ("**PD**") drug formulation work completed and the stability results are very promising.
- Complex Regional Pain Syndrome ("**CRPS**") drug formulation work has also been completed with equally positive stability results.
- A specialty inhalation trial batch manufacturer has been formally engaged for the PD programme, with a technical transfer process being mapped.
- The CRPS manufacturing partner is in the late stage of engagement.
- The US Food & Drug Administration ("**FDA"**) pre-IND meeting for the Panic Disorder programme occurred on the 20th October 2022. The feedback from the FDA was reassuring with the formal meeting minutes expected to be available to the Company within the coming weeks.
- A CRO selection committee has been established to oversee a tender for the appointment of Contract Research Organisation ("**CRO**") for the purposes of the conduct of the planned PD and CRPS clinical trials. The tender process is expected to be completed by the end of November 2022.
- White label sales of Medihale continue and the Company has experimented with other delivery devices (aside from Voom) in order to acquire market insights and information from the medical community device preferences.

The net cash outflow from operating activities during the quarter was $371k, with the Company incurring $180k of research and development expenditure in relation to drug formulation and regulatory advice in preparation for its planned CRPS and PD clinical trials. The Company continues to apply a disciplined approach to the incurrence of operational expenditure.

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Management and board changes

On 27th September 2022, the Company announced the appointment of Dr John Crock as a newly appointed non-executive director and completed a series of management changes in preparation for execution of its clinical trial programmes. These changes included Mr Darryl Davies accepting the appointment as Chief Executive Officer ("**CEO**") of the Company and Dr Rob Jenny being appointed Chief Scientific Officer of the Company.

Dr Crock is a highly experienced plastic surgeon with over 40 years of clinical experience. He has been heavily involved in local and international medical education and has completed an MD thesis which has been published in international journals. Dr Crock has also presented at major scientific forums locally and overseas and has been an active member of a number of medical advisory boards.

Dr Crock intends to leverage his deep wealth of clinical experience and his extensive network of medical connections to help guide the Company through its clinical development programmes. He will be heavily involved in planning and evaluating the clinical aspects of these programmes.

Mr Davies has a strong background of over 16 years in psychology, harm minimisation and healthcare commercialisation, having successfully scaled up a wellness device company and co-founded private medicinal cannabis service provider, Cannvalate Pty Ltd ("**Cannvalate**"). Mr Davies is also a director and co-founder of Cannvalate's specialist cannabinoid and psychedelics CRO, INGENū CRO Pty Ltd ("**INGENū**").

Mr Davies joined the IRX board as a non-executive director in July 2021 and assumed the role of Executive Director in December 2021. As CEO, Mr Davies will take full operational responsibility for delivering the clinical development programme and continuing to grow the Company's medical devices business.

Upon accepting the CEO role, Mr Davies stepped down from his role as an executive director allowing a separation between his operational focus and managerial responsibilities and the board's focus on governance and oversight of the strategic execution of the Company's clinical development programmes and plans for growing its medical devices business.

Dr Rob Jenny is a biochemist and holds a PHD and MBA with experience in R&D, pharmaceutical manufacturing and numerous commercialisation ventures involving universities, start-ups, pharmaceutical and personal care manufacturers.

Dr Jenny will be responsible for overseeing the scientific, regulatory and technical transfer process with a view to ensuring that the clinical development programmes are delivered in a timely, effective and efficient manner.

Clinical development pathway - general up-date

The Company's core focus for the September 2022 quarter has been on refining the regulatory pathway with the FDA, the development of inhaled cannabinoid formulations for the treatment of CRPS and PD, and setting up the manufacturing partnerships for the sourcing of the drug-device combinations in preparation for each of the clinical trial programmes.

The overarching goal is to achieve a New Drug Approval (**NDA**) with the 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 and continues to work with Premier Consulting (formerly Camargo Pharmaceutical Services) which has extensive experience within the chosen regulatory FDA 505(b)(2) pathway.

Formulation: IRX is working closely with a UK-based drug formulation specialist tasked with the development of medications to be dispensed via pressurised metered dose inhalers (**pMDI**) for the treatment of CRPS and PD. The formulation work has been completed across both programmes and the 3 month stability data is very promising.

Manufacturing: An Australian based contract manufacturing partner has been selected to produce the drug / device (pMDI's) combination products for the Panic Disorder programme. It is expected that the engagement of the manufacturer will be formalised in the coming weeks.

Contract Research Organisation (CRO): During September 2022 the Company commenced a tender process involving a number of local and international CRO's for the purpose of selecting a CRO to conduct its planned PD and CRPS clinical trials. The tender process has been overseen by a tender selection committee comprising the Company's independent non-executive directors and an independent UK based specialist CRO consultant.

It is expected that a final decision on the CRO tender will be announced by the end of November.

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 the required formulation work, with solubility and spray characteristics now determined. Ongoing stability testing is underway and the results obtained so far, based on a 3-month time point, are very encouraging. The individual pMDI device componentry has been determined and procurement has commenced.

Clinical Trial: Preparations for the commencement of the Phase 2 (proof-of-concept) trial are on track with the first patient anticipated to be between Feb-April 2023. The investigator's brochure (**IB**) and the clinical trial protocol are well advanced in their preparation.

Regulatory: IRX has continued to work with Premier Consulting towards a NDA with the FDA. Premier Consulting has performed a detailed regulatory assessment of IRX's drug-device candidate. The pre-Investigational New Drug (**Pre-IND**) meeting with the FDA was held on the 20th October 2022 and the sentiment was very positive. Formal minutes are expected to be provided by the FDA within 30 days of the meeting. An Investigational New Drug (**IND**) number has been recently issued to IRX by the FDA in anticipation of this meeting (163026).

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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: The formulation is complete with very promising 3 month stability results. The components have been determined and the process of procurement has commenced.

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 anticipated to be between Feb-April 2023 for the Phase 1 and June-August 2023 for the Phase 2. The clinical trial protocol and the IB have both been 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. This date is yet to be determined.

An Orphan Drug Designation (**ODD**) has been filed with the FDA for CRPS. IRX has received a response from the FDA, in light of this information, 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). It is anticipated that a renewal for 2023 will be issued without concern.

The Company has also now applied for the 2023 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 before the end of the calendar year.

White label opportunities for Medihale

IRX continues to develop its Medihale vape device offering and has been working with various heat (not burn) inhalation device systems to better understand the advantages and shortfalls of existing products that are available in the market.

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

The Company has ceased sales of the Voom device and written off the remaining stock as it has identified tried and tested products that are far superior at delivering cannabinoid medications. The Company expects to provide further information on the new products it plans to distribute to the market in the December quarter.

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:

- $180k in clinical development costs (including medical writing, regulatory engagement and drug formulation costs);
- $84k in ASX, share registry, legal, tax and audit related costs;
- $84k in director fees (including executive director fees);
- $4k for sales and marketing;
- $24k in general corporate costs including consultants ($14k) and German subsidiary winding-up costs ($4k).

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*
3. *https://adaa.org/understanding-anxiety/facts-statistics*
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