31 July 2024

ASX Announcement

QUARTERLY ACTIVITIES, CASHFLOW REPORT and OPERATIONS UPDATE

Quarter ended 30 June 2024

InhaleRx Ltd (ASX: IRX), ('**InhaleRx', 'IRX'** 'or '**the Company'**) an Australian healthcare company developing unique inhaled medicinal drug-device products to address unmet medical needs in pain management and mental health sectors, is pleased to provide its quarterly activities, cash flow report and an update of operations.

Operational highlights are as follows:

- Cash reserves at 30 June 2024: $331k.
- Net cash generated in the quarter for operating activities: $402k.
- The final Clinical Study Report ('**CSR**') was provided as planned by Ingenu CRO Pty Ltd ('**Ingenu**') as the Contract Research Organisation ('**CRO**') in Q2 2024.
- The Company has received insights and operational feedback on the IRX211 protocol from a palliative specialist Key Opinion Leader ("**KOL**"). This real world experience has been very beneficial as we prepare for a Human Research Ethics Committee ('**HREC**') submission to run the Phase 2 trial which will investigate the safety and efficacy of IRX211 with patients who have a Breakthrough Cancer Pain (**'BTcP'**) diagnosis. We anticipate being able to lodge to ethics for the Phase 2 in Q3 2024.
- The Company has completed Food and Drug Administration ('**FDA**') Pre- Investigational New Drug ('**IND**') meetings for both the IRX616a and IRX211 indications and a significant amount of work was completed in the preparation of an IND submission for IRX616a, which was completed during the quarter. The Company recently received formal notification from the FDA that its IND submission for IRX616a will require further evidentiary support and is in the process of considering its options and next steps in advancing this application.
- The Company has prepared all of the information required for a Phase 1 HREC submission for IRX616a after taking account of the valuable insights from the Phase 2 HREC application that was lodged in Q4 2023. All medical writing is now complete, and IRX will shortly commence a tender process to select a CRO partner for this study.

- The Company entered into a Loan Agreement with Peak Asset Management on 27 March 2024 with $250k to be available immediately and a further $250k draw down available in September 2024. $190k of the 1st drawdown was received in the March 2024 quarter, with $10k received during the June quarter. The balance of $50k remains outstanding.
- The Company lodged its 2023 income tax return earlier in the year and received a refund (inclusive of the R&D tax incentive) of $763k during the quarter. $546k (inclusive of fees and interest) of these funds were applied to the repayment of the Radium Capital finance facility.

The net cash inflow from operating activities during the quarter was $402k largely due to the receipt of a R&D tax incentive of $763k for the 2023 year, with the Company incurring $96k of one-off research and development expenditure in relation to its IRX211 Phase 1 clinical trial.

The Company continues to apply a disciplined approach to the incurrence of operational expenditure.

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Clinical development pathway - general up-date

The Company's core focus for the June 2024 quarter was on:

1. Receipt of the Clinical Study report for the Phase 1 IRX211 clinical trial.
2. Seeking KOL input on the IRX211 protocol and making minor changes to strengthen the trial design in preparation for Phase 2 HREC application.
3. Finalising all medical writing in readiness for commencing the tender process for the Phase 1 HREC application for IRX616a.
4. Completing regulatory work and lodging the filing of an IND application with the FDA for IRX616a.

The Company's overarching goal remains to achieve a New Drug Application ('**NDA**') with the FDA. IRX is committed to driving cost efficiency while delivering outcomes in the shortest time frame possible.

Pain Indication

IRX211 clinical trial program update targeting Breakthrough Cancer Pain

The Phase 1 clinical study report, which was received on 3rd July 2024, highlighted very promising insights from a safety and drug delivery efficiency perspective.

The primary focus for the quarter has been on preparing the HREC application for the Phase 2 clinical trial. A KOL with significant experience managing Breakthrough Cancer Pain has recently reviewed the protocol in anticipation of an HREC submission. The insights shared have been valuable from an operational perspective and minor tweaks have been made to the study design to accommodate this feedback. A Study Order has also been executed with Ingenu so that the clinical trial site is now able to make an application through to HREC. We anticipate being able to consolidate all final feedback on the protocol in the coming weeks and the Company expects to be able to lodge with HREC in Q3 2024.

Formal commencement of the Phase 2 trial is, however, subject to the Company raising appropriate funding.

Mental health indication

IRX616a clinical trial program update targeting Panic Disorder.

Clinical Trial

Preparations continue for a HREC submission for the Phase 1 clinical trial and the Company is ready to commence the tender process to select a CRO partner, clinical trial site and principle investigator.

Regulatory

The Company's recent focus has also been on the refinement of an IND submission for IRX616a, which was lodged during the quarter. The FDA has advised of the suspension pending further action (also referred to

as a 'clinical hold') of the initiation of the clinical trial specifically outlined in the IND application in order to address certain safety concerns for the purposes of ensuring the highest standards of patient safety. A clinical hold is a standard regulatory action that occurs when the FDA identifies potential risks, concerns or requires further information relevant to a clinical study.

Furthermore, as the suspension applies only to the trial specified in the IND application, the Company expects to be able to continue (subject to obtaining local Human Research Ethics Committee approval) with its drug development plans in Australia, most notably with its plan to conduct a Phase 1 (PK/Safety) trial for IRX616a.

The Company has now received the formal notification letter from the FDA which outlines the further requirements for the IND's approval and is currently reviewing its options for advancing the application.

Capital requirements

The Company's Board entered into a $500k Convertible Loan Facility (Facility) with Peak Asset Management ('**Peak**') on 27th March 2024, with the first drawdown ($250k) available in Q1 2024, while the remaining drawdown is scheduled to take place in Q3 2024. IRX received $190k in the March quarter from the first drawdown, with a further $10k relating to the first drawdown received during the quarter. The remaining $50k remains outstanding.

The Company continues to develop its plans for raising additional capital in order to execute on its clinical development programs within the anxiety and pain.

The Company is working closely with nominated partners to lodge HREC applications for IRX211 Phase 2,with the intent of having an ethics approval in place so that the management team is ready to commence the clinical trial, subject to raising further capital.

For IRX616a, we are planning to run a tender process to select the relevant CRO and Site partners to conduct the Phase 1 trial.

Payments to Directors & Related Parties

Cash payments to Directors during the June 2024 quarter totaled $63k (including GST) with a further $58k (including GST) paid as salaries to key personnel and contractors.

Use of funds

The Company received an R &D tax incentive of $763k following the lodgement of its 2023 income tax return. $546k of these proceeds were paid to Radium Capital in repayment of IRX's forward financing facility. There was also an ATO net refund received of $11k related to GST and $4k in interest income.

During the quarter, funds spent on operating activities comprised:

- $96k in clinical development costs (including CRO payments, medical writing, regulatory engagement and trial drug manufacturing);

- $177k in general corporate costs including: audit ($38k); IP/legal ($36k); tax and accounting ($34k); insurance ($26k); expert report ($15k); CFO ($13k); company secretary ($11k); and share registry/ASX/ASIC costs ($5k);
- $37k in interest & finance costs related to the Radium forward financing facility
- $22k in director fees;
- $39k in salaries paid to employees; and
- $5k in administration costs.

GST is included in the amounts noted above as applicable.

The Company will provide further updates in due course.

Authorised by the Board of Directors.

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

InhaleRx Limited is an Australian healthcare company which is developing unique medicinal drug-device products to address unmet medical needs in pain management and mental health sectors.

The overarching goal is to pursue U.S. FDA approval and registration using rapid and cost-effective regulatory pathways, such as 505(b)(2).

There is a significant economic opportunity for IRX and the Company's shareholders. The first medical indications under investigation are Breakthrough Cancer Pain ('**BTcP'**) and Panic Disorder ('**PD'**), both of which currently have limited safe and effective treatment options.

IRX holds an innovation patent and provisional patents for the nominated indications and the Company plans to continue to strengthen this position.