22 July 2025

ASX Announcement

QUARTERLY ACTIVITIES, CASHFLOW REPORT and OPERATIONS UPDATE

Quarter ended 30 June 2025

InhaleRx Ltd (ASX: IRX), ('**InhaleRx', 'IRX'** 'or '**the Company'**), an Australian drug development company developing novel inhaled medicines, is pleased to provide its quarterly activities, cash flow report and an update of operations.

IRX currently has two drugs under development:

1) IRX-211, which is a treatment for breakthrough cancer pain ('**BTcP**'); and
2) IRX-616a, a treatment for panic disorder ('**PD'**).

The Company's planned clinical trial program will be among the first clinical trials involving inhaled cannabinoid medications for treating pain and anxiety related conditions. IRX's end goal is a grant from the US Food & Drug Administration ('**FDA'**) of a New Drug Approval ('**NDA**') for each indication.

Operational highlights are as follows:

- A Human Research Ethics Committee (**'HREC'**) resubmission for the stage 2 clinical trial of IRX-211 was submitted, with approval granted swiftly and with minimal queries.
- Manufacturing of the trial drugs for the IRX-211 phase 2 trial commenced as scheduled, with Ingenu CRO ('**Ingenu'**) commencing the clinical site activation work to align with the availability of the trial drugs.
- A Letter of Intent ('**LOI'**) was executed with the leading phase 1 clinical site, CMAX in Adeliade, for commencement of clinical operations for IRX-616a, including preparation of the HREC submission.
- Completed first drawdown under its $38.5m funding agreement with Clendon Biotech Capital Pty Ltd ('**Clendon'**). This will allow the Company to accelerate its drug development plans for IRX-211 and IRX-616a through to Phase 3 readiness. The first drawdown of $248k is being applied to the payment of trial drug manufacturing expenses.
- Received $402k under the Australian Government Department of Industry's Research & Development Incentive ('**RDTI**') for the 2024 financial year. An RDTI amendment was also lodged for 2023 year which resulted in an additional receipt during the June quarter of $93k (including $6k of interest).

The net cash inflow from operating activities during the quarter was $170k with the Company receiving RDTI cash rebates related to the 2024 year during the quarter. The Company continues to apply a disciplined approach to the incurrence of operational expenditure.

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Clinical development pathway – general update

Activities continue to track as anticipated relative to established plans across both the IRX-211 and IRX-616a clinical development programs.

The Company's core focus for the June 2025 quarter was:

1. Working closely with the lead site in Melbourne for the Phase 2 IRX-211 trial in preparation for First Patient In ('FPI') – scheduled for Q3 this year.
2. Engaging with additional Australian sites to accelerate recruitment and execution of the IRX-211 Phase 2 trial.
3. Manufacturing of the IRX-211 trial drugs; and
4. Detailed planning for clinical operations activities, in conjunction with the appointed clinical trial site for the Phase 1 clinical trial, CMAX in Adelaide.

The Company's overarching goal remains to achieve an NDA with the FDA. IRX is committed to driving cost efficiency while delivering outcomes in the shortest time frame possible.

Pain Indication

IRX-211 is Phase 2 ready

There is currently no non-opioid, inhaled treatments approved by the FDA to treat BTcP. Furthermore, the rapid onset treatment options that are available involve fentanyl-based treatment options which have been recently withdrawn in the USA due to safety concerns.

The focus for the June 2025 quarter was on the following:

1. Additional clinical trial sites being evaluated and qualified with the focus on developing alternative avenues to speed up the recruitment rates and ultimately close out the Phase 2 trial as quickly and efficiently as possible.
2. Manufacturing of the placebo and stability program commenced under Ab-Initio Pharma in Sydney, with the manufacturing of active batch planned for the coming weeks.
3. A resubmission to HREC was prepared given the changes in the clinical trial sample size to increase the probability of achieving an efficacy signal. An approval was granted by HREC faster than anticipated and without queries.

The next steps in the IRX-211 Phase 2 clinical trial program are:

1. Site activation and training at the lead site in Melbourne.
2. Completion of the active trial drug batch manufacturing and formal release of the trial drugs by Ab-Initio Pharma.
3. The delivery of the Investigational Medicinal Product ('IMP') (trial drugs) to the clinical trial sites.
4. Screening and dosing of patients.

Mental health indication

IRX616a Phase 1 ready

A Phase 1 clinical trial Study Order has now been executed with the CRO partner, and the refinement of the GMP manufacturing procedures (i.e. specification adjustment) work for the trial drugs has been completed, which is a pre-condition to the commencement of manufacturing of the IMP.

The focus for the June 2025 quarter was on the following:

1. The appointed clinical trial site, CMAX in Adelaide, has commenced clinical operations planning and preparations.
2. An application to HREC is imminent, and the Company is prepared to respond to any queries quickly and efficiently to increase the probability of achieving FPI during Q4.
3. A work order with the manufacturer, Ab-Initio Pharma, was executed during the quarter.

There are currently no treatment options approved by the FDA for this condition.

Capital management

The Company continues to evaluate opportunities for raising further capital to meet its working capital requirements, with the confidence that well over 90% of its forecast expenditure over the next 2-3 years (being clinical development program expenditure) is already fully funded under the Clendon facility.

Clendon Funding Agreement

In October 2024, IRX entered into a $38.5 million funding facility (**the Funding Agreement**) with Clendon which will fully cover the clinical trial costs, including the associated non-clinical work and trial drug manufacturing costs for its IRX-211 and IRX-616a drug development plans through to the completion of Phase 2 clinical trials.

A drawdown was effected in the amount of $248k during the June quarter to cover trial drug manufacturing requirements for the IRX-211 phase 2 trial drugs. Additional drawdowns for expenditure under both the IRX-211 and IRX-616a development programs expected shortly.

Payments to Directors & Related Parties

Cash payments to Directors (current and former) during the March 2025 quarter totaled $20k (including GST) with a further $10k paid as salaries to key personnel.

Use of funds

The net cash inflow from operating activities during the quarter was $170k. The Company received $489k in RDTI receipts, an ATO net refund of $8k related to GST during the quarter and $6k in interest.

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During the quarter, funds spent on operating activities comprised:

- $196k in clinical development costs;
- $107k in general corporate costs, including: audit ($34k); insurance ($25k); Expert's Report ($17k); share registry & ASX ($16k); tax ($10k); CFO ($4k); and other costs ($1k);
- $20k in directors fees to current and former board members; and
- $10k in salaries paid to employees.

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.

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

InhaleRx Limited is an Australian clinical stage drug development company which is developing rapid onset, inhaled therapies to address unmet medical needs in the pain management and mental health sectors. The Company has secured a funding facility of up to $38.5m to accelerate the development of IRX-211 to treat Breakthrough Cancer Pain ('**BTcP'**), and IRX-616a to treat Panic Disorder.

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 InhaleRx and the Company's shareholders, as the clinical indications under investigation have been carefully selected in consultation with regulatory authorities. Bringing new approved medications to market will address critical gaps where there's currently mismatched treatment options that can carry dependency concerns.