28 April 2025

ASX Announcement

QUARTERLY ACTIVITIES, CASHFLOW REPORT and OPERATIONS UPDATE

Quarter ended 31 March 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 some of the first clinical trials involving inhaled cannabinoid medications for treating pain and anxiety related conditions. IRX's end goal is the granting by the US Food & Drug Administration (**FDA'**) of a New Drug Approval (**NDA**') for each indication.

Operational highlights are as follows:

- The Company completed the first draw down under its $38.5m funding agreement with Clendon Biotech Capital Pty Ltd ('**Clendon'**). This funding will allow the Company to accelerate its drug development plans for IRX-211 and IRX-616a through to Phase 3 readiness. The funding was applied to the payment of trial drug manufacturing expenses.
- The Company lodged its 2024 income tax return, inclusive of its claim under the Department of Industry's Research & Development Incentive ("**RDTI**") scheme for the 2024 year and expects to receive a cash payment from the Australian Taxation Office of $402k shortly.
- The Company executed a revised Study Order for IRX-211 which incorporates an expanded trial scope and design. The sample size has increased significantly to 156 with a target of 78 to complete (versus the previous trial design of 60 with a target of 24 to complete) with a view to improving the statistical significance of the trial data. This change represents a significant opportunity for the Company to accelerate the drug's development timeline, potentially reducing the need for a separate Phase 3 trial and expediting the path to market.
- The Company has successfully completed the requisite specification adjustment work for both IRX-211 and IRX-616a in order that the trial drugs are appropriately re-formulated to the precise requirements of the proposed trials. Manufacturing can now commence once approval is received from the Human Research Ethics Committee (**HREC**').
- The Company executed a work order to commence trial drug batch manufacturing for IRX-211 and timelines for commencement are being confirmed in consultation with the clinical trial site.
- The Company also executed a Study Order for IRX-616a to conduct the planned Phase 1 clinical trial of safety and tolerability in healthy volunteers.

InhaleRx Limited (ACN 611 845 820)
Level 9, 505 Little Collins Street,
Melbourne, Victoria 3000
Phone: +61 3 8678 4091

The net cash outflow from operating activities during the quarter was $131k with the Company continuing to apply a disciplined approach to the incurrence of operational expenditure.

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.

With this strategic support, IRX is well positioned to accelerate the development of breakthrough inhaled therapies for patients with unmet medical needs, including its clinical development plans for IRX211 and IRX616a. It will also enable IRX to address the requirements of the FDA relevant to its recent IRX-616a Investigational New Drug ('**IND'**) application.

The Funding Agreement is for a headline amount of $38.5 million (which does not take account of the available RDTI funding) and allows for the drawdown of funding as eligible expenditure is incurred. However, it is expected that the overall level of expenditure will be well below the headline facility limit.

As a condition precedent under the Funding Agreement, Clendon was issued options which equate to approximately 20% of the total ordinary shares on the day it was announced (12 October 2024). These options provide an important mechanism for the repayment of the Clendon loan facility as they have a vesting window which aligns with the planned completion of the phase 2 clinical programs for each of IRX-211 and IRX-616a.

IRX's objective is to ensure that the value of these medications as Phase 3 ready assets are properly reflected in its share price at the time that the options vest, in order that Clendon's exercise of the options at a 10% discount to IRX's 90-day Volume Weighted Average Price ('**VWAP'**) will generate sufficient proceeds to repay the loan.

The Company has worked closely with Clendon during the quarter to plan out the clinical development activities, timelines and anticipated expenditure for 2025 and 2026.

Clinical development pathway - general up-date

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

1. Completing the tender process and securing shareholder approval to enable the Company to execute Study Orders for the IRX-211 (Phase 2) and the IRX-616a (Phase 1) clinical trials with Ingenu CRO Pty Ltd ('**Ingenu'**). Approval was received at an Extraordinary General Meeting on 6 March 2025.

2. Completing all contractual conditions precedent under the Clendon Funding Agreement and attending to all administrative requirements to allow the first draw down to proceed. The first drawdown was effected on 23 April 2025 for $247k, which was applied to GMP batch manufacturing of the trial drugs for the IRX-211, Phase 2 clinical trial.

3. Amending and improving to the IRX-211 Phase 2 clinical trial protocol following biostatistical input to the trial design with the intention of improving the probability of achieving statistical significance for the trial outcomes.

4. Completing the required specification adjustment via IRX's formulation specialist in the UK so that the trial drug formulations for IRX-211 and IRX-616a are appropriately aligned with the precise requirements for the forthcoming clinical trials.

5. Procurement of the remaining componentry for the manufacture of the Pressurised Metered Dose Inhalers ('**PMDi'**) in preparation for pilot and clinical batch manufacturing of the trial drugs.

6. Continuing to investigate and evaluate potential clinical service provider partners for completion of the required highly complex, non-clinical inhaled toxicology work for IRX-211 and IRX-616a for the Company to satisfy FDA phase 3 readiness requirements.

The Company's overarching goal remains to achieve a 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

IRX-211 is IRX's BTcP medication. There are 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 execution of the revised Study Order with Ingenu, activation of the first draw down of the Clendon facility, and the execution of the work order with the trial drug manufacturer are significant milestones that demonstrate IRX's progress towards the commencement of patient dosing for its Phase 2 clinical trial.

The recent changes to the trial protocol represent an upgrade in the sample size so that the trial design now more broadly aligns with that of a pivotal trial. The sample size has increased significantly to 156 with a target of 78 to complete (versus the previous trial design of 60 with a target of 24 to complete). This change represents a significant opportunity for the Company to accelerate the drug's development timeline, potentially reducing the need for a separate Phase 3 trial and expediting the path to market.

This change in the trial design reflects the increased opportunity available to the Company to optimize its clinical trial program following the establishment of the Clendon facility.

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

1. Re-submission to HREC of the revised trial protocol.
2. Site Initiation Visits to activate the clinical trial sites.
3. Completion of trial drug batch manufacturing and the long-term stability testing.
4. The delivery of the Investigational Medicinal Product ('**IMP'**) (trial drugs) to the clinical trial sites.
5. Screening and dosing of patients.

The HREC resubmission is expected to be completed in early May 2025.

Mental health indication

IRX616a Phase 1 ready

IRX-616a is IRX's PD medication. There are currently no treatment options approved by the FDA for this condition.

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 Company is working closely with the Ingenu as the CRO partner and CMAX as the clinical trial site to lodge for HREC as soon as possible.

Upon completion of the Phase 1 trial, the Company will submit an HREC application to proceed with the Phase 2 clinical trial in PD patients.

Capital management

The Company has completed and lodged its 2024 income tax return, inclusive of its claim under the Department of Industry's RDTI scheme for the 2024 year, and expects to receive a cash payment from the Australian Taxation Office of $402k shortly.

The Company continues to evaluate opportunities for raising further capital to meet its working capital (operational) 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.

Payments to Directors & Related Parties

Cash payments to Directors (current and former) during the March 2025 quarter totaled $33k (including GST) with a further $10k paid as salaries to key personnel.

Use of funds

The net cash outflow from operating activities during the quarter was $131k. The Company received an ATO net refund of $56k related to GST during the quarter.

During the quarter, funds spent on operating activities comprised:

- $73k in general corporate costs, including: insurance ($32k); legal (IP related) ($21k); audit ($11k); CFO ($4k); company secretary ($3k); and other costs ($2k);
- $70k in clinical development costs;
- $33k in directors fees to current and former board members;
- $10k in salaries paid to employees; and
- $1k paid for investor relations.

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:
www.inhalerx.com.au

James Barrie
Phone 03 8678 4091

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

InhaleRx Limited is an Australian drug development 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.