31 October 2025

ASX Announcement

QUARTERLY ACTIVITIES, CASHFLOW REPORT and OPERATIONS UPDATE

Quarter ended 30 September 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, 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:

- The Company sought alignment with the FDA guidelines, effectively via a truncated Pre-Investigational New Drug application ('PIND') in a Written Responses Only ('**WRO'**) format in order to reaffirm its proposed clinical development plans for IRX-211 as a treatment for BTcP (previous FDA guidance was for Complex Regional Pain Syndrome ('**CRPS'**)).
- A Human Research Ethics Committee (**'HREC'**) resubmission for the Phase 2 clinical trial of IRX-211 was submitted which took account of slight changes to the trial design and documentation resulting from the FDA guidance , with approval granted swiftly and with minimal queries.
- A Letter of Intent ('**LOI'**) was executed with the leading phase 1 clinical site, CMAX in Adelaide, for commencement of clinical operations for IRX-616a, including preparation of the HREC submission.
- A HREC approval for the Phase 1 clinical trial IRX-616a was received via CMAX.
- 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.

The schedule was also confirmed for the manufacturing of the trial drugs for the IRX-616a phase 1 trial.

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Clinical development pathway – general update

Activities are progressing well across both the IRX-211 and IRX-616a clinical development programs as we prepare for screening and dosing.

The Company's core focus for the quarter ending 30 September 2025 involved:

1. Working closely with the lead site in Melbourne for the Phase 2 IRX-211 trial in preparation for First Patient In ('**FPI'**).
2. A PIND submission seeking consultation with the FDA to validate the Phase 2 IRX-211 trial design and primary endpoints required for a treatment for BTcP, prior to the commencement of the Phase 2 trial.
3. Obtaining HREC approvals for both IRX-211 to commence the Phase 2 trial following a resubmission, and IRX-616a to commence the Phase 1 trial.
4. Engaging and qualifying additional Australian sites to accelerate recruitment and execution of the IRX-211 Phase 2 trial.
5. Manufacturing of the IRX-211 trial drugs; and scheduling IRX-616a manufacturing for Q4.
6. Detailed planning for clinical operations activities, in conjunction with the appointed clinical trial site for the IRX-616a 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. There is an estimated $10.98b USD Total Addressable Market ('**TAM'**) specifically for the cancer pain market by 2028[1].

IRX-211 is the more advanced clinical asset within the IRX portfolio with a Phase 2 trial targeting dosing of BTcP suffers about to commence.

A PIND meeting was held in March 2023 with the FDA for IRX-211, when it was being developed as a breakthrough pain treatment for patients suffering from CRPS. At the time, Phase 1 PK and safety data were not yet available, and FDA feedback was based on the proposed package to enable a Phase 2 study in patients with CRPS.

Following completion of the Phase 1 PK/safety study and after feedback from the FDA via the PIND, the program transitioned to BTcP – a setting involving opioid-tolerant cancer patients with different safety, drug-interaction, and regulatory considerations.

[1] https://www.globenewswire.com/news-release/2023/09/28/2750975/28124/en/Global-Cancer-Pain-Market-2023-2028-Eli-Lilly-Company-and-Johnson-Johnson-at-the-Forefront-of-Personalized-Pain-Management-for-Cancer-Patients.htm

Prior to commencing the Phase 2 trial for IRX-211 as a treatment for BTcP, IRX sought further FDA input – effectively a truncated PIND in WRO format in order to ensure that its proposed clinical development pathway, and specifically Phase 2 trial design, was optimal relative to FDA guidelines for BTcP. Conducting a second PIND ensured regulatory alignment for the new indication and de-risked the BTcP program ahead of clinical initiation — marking a major milestone in the development of this rapid-onset analgesic for breakthrough cancer pain.

The WRO was submitted in early September 2025, and the relevant FDA feedback was incorporated into the clinical trial design. The agency's comments informed refinements to endpoints, inclusion criteria and safety monitoring. While not significant from a trial design perspective, the FDA refinements did necessitate the amendment of some aspects of the trial protocol and related documentation with the result that IRX was obliged to submit a further HREC submission for approval of the amended trial.

This engagement led to a slight delay compared to timelines previously communicated to the market, as the identified clinical trial sites were unable to commence the trial planning and training of site personnel until the HREC approval for the amended protocol was received.

HREC approval was obtained for the amendments on 21 October 2025, positioning IRX-211 to advance into patient studies. The updated trial protocol and documentation have now been provided to the identified trial sites e.g. Vitalis (lead site), GenisisCare, Braeside Hospital and Liverpool Hospital, with the sites presently attending to their internal compliance and operational procedures ahead of the commencement of screening and dosing of patients.

It is now expected that screening of BTcP patients will commence in November, with First Patient In and First Patient First Dose to be completed before year end.

The planned design for the ethics approved Phase 2 trial is a double-blind, placebo-controlled, multicenter, crossover study with titration period to evaluate the efficacy and safety of IRX-211 for the treatment of BTcP in opioid tolerant patients. The trial is in two parts:

- Part A: Titration period – An open-label titration phase
- Part B: Double-blind, placebo-controlled, cross-over phase

A total of 156 patients diagnosed with cancer and experiencing one or more BTcP episodes on at least seven days of the 14-day baseline observation period will be enrolled in the open-label titration period stage of the trial – Part A.

Patients who do not report an effective individualised dose during the 3-week titration period (Part A) will not continue into Part B (i.e. will be excluded from the study). Patients who achieve effective pain relief (assessed subjectively by the patient) for two consecutive BTcP episodes which are treated with IRX-211, will enter the double-blind, randomised, placebo-controlled, cross-over Part B phase.

At least 78 eligible patients are planned to be randomised and entered into Part B.

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The focus for the quarter ending 30 September 2025 for IRX-211 was on the following:

1. Manufacturing of the pilot batch, first active and placebo batches of the trial drug by Ab-Initio Pharma in Sydney in preparation for screening and dosing.
2. Additional clinical trial sites were 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.
3. The WRO was prepared and submitted to the FDA for the BTcP PIND with formal FDA feedback received in October.
4. A resubmission was lodged with HREC to consider the protocol changes following the feedback from the FDA.
5. Ethics approval received.

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

1. Site activation and training across all qualified Australian sites.
2. The delivery of the already manufactured Investigational Medicinal Product ('**IMP'**) (trial drugs) to the clinical trial sites.
3. Screening and dosing in the patient population.
4. Planning for the second batch of manufacturing to ensure continuity of trial supply.

Mental health indication

IRX-616a Phase 1 ready

IRX-616a is targeting the development and commercialsation of a registered prescription-only medication to treat Panic Disorder.

There are currently no FDA approved drugs for treating Panic Disorder via inhalation, and there is an estimated $13.3b USD TAM for anxiety disorders and depression treatments by 2027[2].

In terms of trial design, IRX has HREC approval for a Phase 1, randomised, double-blind, placebo-controlled single ascending dose study to assess the pharmacokinetics, safety and tolerability of cannabidiol ('**CBD'**) inhalation aerosol in healthy adult volunteers.

The study will consist of three phases: Screening, Treatment, and Follow-up. The clinical trial will include approximately 3 cohorts of 8 volunteers (1 cohort per dose level) prescheduled in a sequential ascending manner.

[2] https://www.globenewswire.com/news-release/2022/06/13/2460905/0/en/Anxiety-Disorders-and-Depression-Treatment-Market-Size-worth-USD-13-03-Billion-by-2027-at-CAGR-of-2-6.html

The focus for the quarter ending 30 September 2025 was on the following:

1. Initiating and activating the clinical trial site, CMAX in Adelaide.
2. Trial batch manufacturing of the placebo, noting that the active is already scheduled for Q4.
3. Planning for the Phase 2 trial that the Company is aiming to execute in quick succession following the completion of the Phase 1.
4. Coordinating a timeline for site activation that considers the availability in terms of the manufacturing schedule.

Capital management

The Company continues to evaluate opportunities for raising further funds 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.

The net cash outflow from operating activities during the quarter was $310k. The Company continues 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.

The Company has recently entered into an assignment deed at Clendon's request which transfers the Funding Agreement to a new funding entity, Linlithgow Family Office Pty Ltd **('LFO')**. There was no material change to the Funding Agreement resulting from this assignment.

Payments to Directors & Related Parties

Cash payments to Directors (current and former) during the September 2025 quarter totaled $30k (including GST) with a further $15k paid as salaries to key personnel. The payments to Directors related to remuneration related to the 2024 year with all current year entitlements to be paid in the form of performance rights as per the shareholder approval at the 2024 Annual General Meeting in May 2025.

Use of funds

The net cash outflow from operating activities during the quarter was $310k. The Company received ATO net refunds totaling $77k related to GST during the quarter.

During the quarter, funds spent on operating activities comprised:

- $146k in clinical development costs;

- $197k in general corporate costs, including: tax and audit ($52k); CFO ($38k); company secretary (for 2024 and current year)($30k); share registry & ASX ($33k); insurance ($32k); legal (patents)($6k) and other costs ($6k);
- $30k in directors fees (related to 2024); and
- $15k 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.