



24 January 2025

## ASX Announcement

### **UPDATED QUARTERLY ACTIVITIES REPORT and OPERATIONS UPDATE**

*Quarter ended 31 December 2024*

InhaleRx Ltd (ASX: IRX), ('InhaleRx', 'IRX' or 'the Company') an Australian drug development company specialising in inhaled medicines to address unmet medical needs in pain management and mental health sectors, refers to its Quarterly Activities Report for the Dec24 quarter lodged on ASX 23 January 2025.

The Company has since become aware a superseded version was inadvertently lodged.

Attached on the following pages is the correct version, noting there is no change to the Appendix 4C also lodged 23 January 2025.

The Company apologises for this oversight and any confusion caused.

Authorised by the Board of Directors.

#### **For further information:**

[www.inhalerx.com.au](http://www.inhalerx.com.au)

James Barrie

Phone 03 8678 4091

#### **About InhaleRx Limited (ASX: IRX) – [www.inhalerx.com.au](http://www.inhalerx.com.au)**

InhaleRx Limited is an Australian biotechnology company developing unique inhaled drug-device treatments 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, or no safe and effective treatment options.

IRX holds an innovation patent and a number of provisional patents lodged for the nominated indications as the Company plans to continue to strengthen this intellectual property position.



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## ASX Announcement

### QUARTERLY ACTIVITIES, CASHFLOW REPORT and OPERATIONS UPDATE

*Quarter ended 31 December 2024*

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 signed a \$38.5m funding agreement with Clendon Biotech Capital Pty Ltd (**'Clendon'**) on 18 October 2024 which will allow the Company to accelerate its drug development plans for IRX-211 and IRX-616a through to the completion of Phase 2 clinical trials.
- The Company received an approval from the Human Research Ethics Committee (**'HREC'**) to commence the Phase 2 trial investigating the safety and efficacy of IRX-211 in patients with BTcP.
- The tender processes have been finalised for the appointment of a Contract Research Organisation (**'CRO'**) to oversee the Phase 1 IRX616a and Phase 2 IRX-211 human clinical trials with Ingenu CRO Pty Ltd (**'Ingenu'**) appointed as the CRO.
- The IRX211 final Phase 1 Clinical Study Report (**'CSR'**) was finalised by and the Trial Master File transferred from the CRO (Ingenu) marking the official completion of the trial (IRX211-001).
- The CSR was reviewed in consultation with IRX's patent attorney, with the resulting filing of a comprehensive international patent application under the Patent Cooperation Treaty (**'PCT'**), designated as PCT/AU2024/051391 for inhaled Breakthrough Cancer Pain (**'BTcP'**) treatment now complete.

The net cash outflow from operating activities during the quarter was \$97k with the Company continuing to apply a disciplined approach to the incurrence of operational expenditure.

## CRO appointment

The Company released separate tenders for the appointment of a CRO to oversee the conduct of its planned Phase 1 IRX616a and Phase 2 IRX-211 human clinical trials in November 2024. The tender processes have been finalised with Ingenu CRO Pty Ltd (**'Ingenu'**) appointed as the CRO.

As Ingenu is a related company to IRX by virtue of it being a majority owned subsidiary of IRX major shareholder, Cannvalate Pty Ltd, the Company has now commissioned an independent expert's report in accordance with the requirements of ASX Listing Rule 10.1 to confirm the fairness and reasonableness of the proposal for non-associated shareholders. An EGM will be scheduled in order that the appointment can be formally considered and approved. It is anticipated that the meeting will be held in late February/early March, subject to the availability of the expert report.

## Clendon Funding Agreement

In October 2024 IRX entered into a \$38.5 million funding facility with Clendon Biotech Capital (**'Clendon'**) (**'the Funding Agreement'**) 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.

Clendon is a Melbourne based venture capital firm specialising in investments in small to mid-size biotechnology companies. With a strategic focus on advancing innovation, Clendon targets therapeutic areas including neuroscience, gastroenterology, oncology and anti-aging.

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 available Research & Development Tax Incentive program (**'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.

The issue of 38,449,145 options to Clendon under the Funding Agreement was approved at an EGM on 28 November 2024 in order to satisfy a key condition precedent under the Funding Agreement.

These options, which equate to approximately 20% of the total ordinary shares on the day it was announced (12 October 2024), 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 December 2024 quarter was on:

1. Analysing the CSR for the Phase 1 IRX-211 clinical trial in order to lodge a PCT patent to improve IRX's Intellectual Property('IP') positioning.
2. Seeking biostatistical input on the IRX-211 Phase 2 protocol with a view to making changes to strengthen the trial design.
3. Initiating tender processes for the appointment of a CRO partner to oversee the conduct of the IRX-616a Phase 1 and IRX-211 Phase 2 clinical trials.
4. Preparing for required specification adjustment work in consultation with IRX's formulation specialist in the UK.
5. Procurement of the remaining componentry for the manufacture of the Pressurised Dose Metered Inhalers ('PMDI') in preparation of pilot and clinical trial batches.
6. Non-clinical, two species inhaled toxicology work is also in the early stages of planning. The Company engaged an independent consultant to assist in defining the non-clinical trial designs. The management team has also been working closely with service providers to refine quotes and timelines.

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**

#### **IRX211 clinical trial program update targeting Breakthrough Cancer Pain**

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 due to safety concerns.

The availability of funding has allowed IRX to revisit the trial through a new and exciting lens, with the result that the trial design has been up-graded so that it now more broadly aligns with that of a pivotal trial, with the sample size increasing to 156 with a target of 78 to complete (versus the previous trial design of 60 with a target of 24 to complete).

This could present a significant opportunity to accelerate the drug's development timeline, reducing the need for a separate Phase 3 trial and expediting the path to market.

## Patent Cooperation Treaty

Following a comprehensive review of the CSR for the Phase 1 clinical trial by IRX's patent attorneys, the Company was able to file a comprehensive international patent application under the Patent Cooperation Treaty (PCT), designated as PCT/AU2024/051391 on 20<sup>th</sup> December 2024.

If the Company successfully navigates this process, having a PCT patent approved will greatly assist it in maximising the commercial value of IRX-211 by protecting it globally against replication by competitors, enabling the Company to scale its operations, secure and commercialise competitive market entry advantages, and achieve sustainable growth in international markets.

A successful PCT application will enhance the Company's patent portfolio and improve IRX's positioning for protection in nominated jurisdictions. By securing IP rights in key international markets, IRX will position itself to deliver proprietary, cutting-edge therapies to a broader market base, while safeguarding its competitive advantage as a first market mover in the growing inhaled drug sector.

Over the next 8-12 weeks, the Company will be commissioning International Search Reports, which provide a preliminary assessment of the patentability of the invention based on prior art (registrations). These reports will also help IRX and its patent attorneys to evaluate and further develop strategies for securing a patent in jurisdictions of interest.

### Key Highlights of the PCT Application:

- **Marketing Exclusivity:** A successful granting of a patent improves the Company's opportunities for claiming exclusivity in developing, manufacturing, and marketing IRX211, assisting the Company in protecting its revenue streams and market position against generic or biosimilar competition.
- **Innovation in Drug Delivery:** The patent covers advancements in inhalation systems designed to improve therapeutic outcomes for BTcP patients.
- **Global Market Reach:** With the PCT application, IRX can target coverage in multiple jurisdictions, ensuring IP protection in regions consistent with its growth strategy for IRX-211.
- **Enhanced R&D Prospects:** The application reflects the Company's dedication to advancing research and development, bolstering its capacity to address unmet medical needs.

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

1. Formal appointment of a CRO partner.
2. Amendment of the approved HREC application to update the trial size.
3. Finalising the procurement of all componentry in preparation for manufacturing.
4. Commencement of the long-term stability program.
5. Site Initiation Visits ('SIV') to activate the clinical trial sites.
6. Clinical trial batch manufacturing.
7. Delivering Investigational Medicinal Product ('IMP') (trial drugs) to the clinical trial sites.
8. Screening and dosing of patients.

## Mental health indication

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

## **IRX616a clinical trial program update targeting Panic Disorder.**

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

In preparation for commencing the Phase 1 trial, the management team has been working closely with IRX's formulation specialist in the U.K to refine the GMP manufacturing procedures (i.e. specification adjustment). This is a pre-condition to the commencement of manufacturing of the IMP.

In parallel, the procurement of all componentry is on track for batch manufacturing.

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.

The Company is focused on lifting the 'clinical hold' imposed by the FDA on its IND application by supplementing its submission with data from its planned non-clinical toxicology studies.

### **Payments to Directors & Related Parties**

Cash payments to Directors during the December 2024 quarter totaled \$nil (including GST) with a further \$10k paid as salaries to key personnel. 5,711,837 shares were issued to IRX current and former directors and the Company's CEO, Mr Darryl Davies, during the quarter in lieu of the payment of directors fees and salary benefits for the year.

### **Use of funds**

The Company received an ATO net refund of \$10k related to GST during the quarter.

During the quarter, funds spent on operating activities comprised:

- \$87k in general corporate costs including: insurance (\$46k); legal (IP & Clendon facility related) (\$15k); share registry/ASX/ASIC costs (\$10k); CFO (\$8k) and company secretary (\$8k);
- \$6k in clinical development costs;
- \$4k paid for investor relations; 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.

### **For further information:**

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