23 January 2025

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 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:

- Cash reserves at 31 December2024: $194k.
- Net cash generated/(used) in the quarter for operating activities: ($97k).
- The Company signed a $38.5m funding agreement with Clendon Biotech Capital Pty Ltd ('**Clendon'**) on 18 October 2024 which fully covers the clinical trial costs, including the associated non-clinical work and trial drug manufacturing costs for the IRX-211 and IRX-616a drug development plans 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.

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

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.

Despite significant initial interest from both local and international CRO's, the Company only received one response to each tender – being from Ingenu. The remainder of the CRO's who signed a Non-Disclosure Agreement and received the tender packs declined to submit responses, either because the proposed trials were regarded as too small and/or specialised or because of concerns about a potential conflict of interest associated with IRX's executive team and advisors relative to their involvement as managers and/or directors of Ingenu.

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 bio-technology 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 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 Clendon facility's headline limit is based on forecast gross clinical development expenditure, which is before any Department of Industry's Research & Development Tax Incentive program ('**RDTI')** proceeds are considered. The Company intends to maximise its access to the RDTI and will utilise RDTI forward funding to gain early access to these proceeds, which will be applied to the reduction of the Clendon loan facility. This will both reduce the overall loan balance and accrued interest costs.

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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.

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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.

With the successful completion of the Phase 1 trial, efforts have shifted toward strategies to de-risk the planned Phase 2 trial. Prior to the Clendon Funding Agreement, the trial design prioritised a small sample size, which focused on minimising cost, whilst still meeting the minimum requirements for a Phase 2 clinical trial to progress to the next stage. As part of the negotiation of the Clendon Funding Agreement, Clendon specifically requested that the IRX management team re-visit the trial design with a view to increasing the likelihood of detecting an efficacy signal which was statistically significant and potentially suitable for use as pivotal data.

The availability of funding has allowed IRX to revisit the trial through a new and exciting lens. IRX subsequently engaged two independent biostatisticians, to review the sample size, with the result that the trial design is now more broadly aligned 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).

Increasing the sample size in the Phase 2 trial demonstrates the Company's commitment to maximising the potential for detecting a clear efficacy signal, which is a critical step in the drug development process. If this expanded trial can yield statistically significant results, the data could potentially meet the rigorous standards required for pivotal data submission to the FDA.

This could, in turn, 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. For shareholders, this strategic decision underscores the Company's focus on value creation by potentially saving time, cost and resources while positioning the therapy as a strong candidate for regulatory approval, and in so doing, enhancing the Company's competitive position.

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 20th 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

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.

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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:
www.inhalerx.com.au

James Barrie
Phone 03 8678 4091

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.