Shareholder Newsletter

Melbourne, Australia, 19 December 2024 – InhaleRx Ltd (ASX: IRX), ('**IRX** 'or '**the Company'**) an Australian drug development company developing novel inhaled medicines is pleased to provide shareholders with an overview of its progress over the past 12 months and its exciting plans for 2025 and beyond as it progresses its clinical trial programs.

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 FDA of a New Drug Approval ('**NDA**') for each indication.

During the 2024 year, IRX completed a successful Phase 1 clinical trial covering safety and pharmacokinetics for IRX-211 and now has ethics committee approval for a planned Phase 2 clinical trial, which it expects to commence in the new year.

The Company has also completed all the necessary preparations for the submission of an ethics committee approval for a planned Phase 1 clinical trial of IRX-616a, which it expects to lodge early in the new year, with the trial to commence shortly thereafter.

IRX is currently completing drug formulation specification adjustments and batch manufacturing work required in the manufacture of the requisite trial drugs for the proposed IRX616a (Phase 1) and IRX-211 (Phase 2) trials.

On August 28, 2024, manufacturers of Transmucosal Immediate-Release Fentanyl ("**TIRF**") medicines announced that production of all TIRF medicines would be discontinued on September 30, 2024. This relates to the FDA Risk Evaluation and Mitigation Strategy ('**REMS**'), and manufacturers have confirmed that they will no longer accept new enrollments for patients, prescribers, or pharmacies within the REMS program.

TIRF medications, including fentanyl, are highly effective for managing severe pain, but their potent effects pose serious risks, such as overdose and death, particularly when prescribed to patients who are not opioid-tolerant. The FDA REMS program aims to ensure these medications are used safely, focusing on restricting access to patients who meet strict criteria. This increased regulation provides an opportunity for IRX-211 to enter the market with a differentiated profile, especially if it can offer similar or improved efficacy in managing breakthrough pain but with a more favorable safety and risk profile.

IRX has positioned IRX-211 as a solution that addresses the limitations of current treatments under the REMS program. With stricter guidelines surrounding the prescription of fentanyl-based products, healthcare

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providers and patients are seeking alternative options for breakthrough cancer pain management that reduce the complexity of opioid-based treatment regimens. IRX-211, if demonstrated to be both effective and safer than TIRF medications, has the opportunity to capture significant market share, particularly among patients who are not suitable candidates for fentanyl-based therapies.

The latest discontinuation announcement reinforces the Company's positioning in an ever-evolving market landscape in which IRX-211 may offer a more accessible and effective treatment option for patients while meeting the FDA's evolving standards.

The Company has spent much of 2024 (and in fact the past 2 years) addressing the funding requirements for its clinical development plans covering IRX-211 and IRX-616a and is very excited to have entered into a funding agreement with Clendon Biotech Capital ('**Clendon'**). The funding will allow the Company to reach the Phase 3 pivotal stage for both IRX-211 and IRX-616a.

This funding will enable IRX to move forward with its clinical development plans for IRX211 and IRX616a. The arrangement will 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. It will also enable IRX to address the requirements of the FDA relevant to its recent IRX-616a Investigational New Drug ('**IND'**) application.

The Clendon funding facility is for a headline amount of up to $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 this headline facility limit. The 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 taken into account. 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.

Shareholder approval of the allocation of options was a key condition precedent for the Clendon funding agreement and an important feature of the arrangement, and we thank shareholders for their strong support of this resolution at the recent General Meeting.

The options that have since been issued to Clendon provide an important mechanism for the repayment of the Clendon facility loan. They equate to approximately 20% of the total ordinary shares on the day it was announced (12 October 2024) and have a vesting window which aligns with the completion of the phase 2 clinical programs for each of IRX-211 and IRX-616a. Our objective is to ensure that the value of these medications as Phase 3 ready assets are properly reflected in IRX's share price at the time that the options vest, such 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.

A key objective for the Company's executive team and board moving forward will be ensuring that the investment market is properly informed about the Company, its objectives and plans, the problems it is trying to solve and the value that can be created through the Company's clinical development programs with a view to ensuring that this is properly reflected in the Company's share price at the time the Clendon options vest.

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It is also important to note that the Clendon funding agreement only provides funding for clinical development expenditure. This means the Company will remain responsible for funding its operational and corporate overheads as these costs are specifically outside the scope of the funding arrangement.

IRX's progress across 2024 was supported by a $500,000 loan facility which was entered into with Peak Asset Management in March 2024. $401,000 was ultimately drawn down under this facility in two tranches between March and October. Under the terms of the loan facility the funding contributors had the right to convert the loan to ordinary shares. This occurred on 18 October 2024 and 17,969,880 shares were issued.

Over the course of 2024, the Company has also taken every opportunity to reduce its operational and corporate overheads. Part of these initiatives has involved our CEO, Mr Darryl Davies, agreeing to accept ordinary shares in lieu of salary and the board agreeing to accept ordinary shares in part payment of their accrued directors fees.

In summary, as IRX heads into 2025, the board and executive team are focused on:

1) Execution of our clinical development programs for IRX-211 and IRX-616a in order to achieve Phase 3 readiness as quickly as a possible within the next 2-3 years;
2) Engagement with existing, new and potential shareholders and investors to:
    a. Ensure that we have sufficient working capital funding to run the Company; and
    b. Increase market awareness of the Company, the problems it is aiming to solve and the value that can be created through this process so that we lift the share price and market capitalisation of the Company; and
3) Development of the commercial relationships and opportunities which will support the Company's clinical development programs through the more complex and expensive Phase 3 (and beyond) stages.

With clinical trial funding in place, the Company moves into an exciting 2025 and beyond. We wish to thank the IRX team and our loyal shareholders for their support and wish all a safe and prosperous festive season.

Authorised by the Board of Directors.

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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.

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