InhaleRx Secures $38,500,000 Funding to Fully Fund Clinical Development Plans

Melbourne, Australia, 18th October 2024 – InhaleRx Ltd (ASX: IRX) ('**InhaleRx' 'IRX'** or '**the Company'**), an Australian healthcare company developing unique drug-device products to address unmet medical needs in pain management and mental health sectors, is pleased to announce that it has entered into a significant funding agreement with Clendon Biotech Capital Pty Ltd ('**Clendon Biotech Capital**'). This strategic partnership will provide the funding to cover all direct costs associated with the Phase 1 & 2 clinical development of the Company's key projects - IRX-211 and IRX-616a.

Highlights:

- **Secured Funding**: InhaleRx has secured a funding facility of up to $38.5 million from Clendon Biotech Capital to fully cover 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.

- **Clinical Progress**: This funding will enable InhaleRx to move forward with its clinical development plans for IRX211 and IRX616a, including non-clinical data. It will also enable IRX to address the requirements of the US Food & Drug Administration ('**FDA'**) relevant to its recent IRX-616a Investigational New Drug ('**IND'**) application.

- **Focus on Transformational Therapeutics**: With this strategic support, InhaleRx is well positioned to accelerate the development of breakthrough inhaled therapies for patients with unmet medical needs.

The funding agreement provides InhaleRx access to up to $38.5 million in funding, which is expected to allow the Company to reach the Phase 3 pivotal stage for both IRX-211 and IRX-616a within the next 2-3 years. The facility allows for the drawdown of funding as eligible expenditure is incurred.

Further details of the Clendon Biotech facility and options included within the proposed funding structure are included in Appendices 1 and 2.

Once approved, the Clendon Biotech Capital facility will allow the Company to immediately activate the specification adjustment 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.

This partnership ensures that InhaleRx can move forward with the next stages of its clinical trials and non-clinical work, including addressing the further requirements outlined in FDA feedback related to its recent IND submission for IRX-616a.

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While it is expected that this funding arrangement will cover all necessary clinical trial costs, InhaleRx will remain responsible for covering its operational and corporate overheads as these costs are specifically outside the scope of the funding arrangement. The Company remains confident in its ability to secure the necessary additional funding to meet these working capital costs and ensure continued operational sustainability.

About Clendon Biotech Capital

Clendon Biotech Capital is a Melbourne based venture capital investor which is keenly focused on small to mid-size bio-technology companies in its target therapeutic areas - neuroscience, gastroenterology, oncology and anti-aging.

The Board of InhaleRx views the partnership with Clendon Biotech Capital as a transformative step in securing the Company's ability to execute its clinical development strategy, which will further position it as a leader in the inhaled therapeutics sector.

IRX's CEO, Mr. Darryl Davies, said: "We are very excited to have Clendon Biotech Capital as a committed funding partner. This agreement enables InhaleRx to focus on advancing our key clinical programs, including addressing the requirements outlined in FDA feedback on our recent IRX616a IND application. While this partnership provides vital support for our clinical development program, we will continue to explore opportunities to fund our broader operational needs and ensure the long-term success of the Company."

The Drug Development Pathway for IRX-211

IRX-211 is a drug-device medication, specifically designed to target breakthrough cancer pain ('**BTcP'**), a condition characterised by sudden, intense episodes of pain that occur despite otherwise controlled cancer related chronic pain.

IRX-211 delivers a precise dose of the medication designed to provide rapid onset relief, ensuring quick absorption and action when needed most.

BTcP can be particularly debilitating for cancer patients, and conventional treatments often fall short due to delayed onset of action or suboptimal dosing. IRX-211 aims to address this gap by providing fast, effective relief, leading to an improvement in the quality of life of individuals suffering with cancer-related pain. By offering a more targeted and efficient solution, IRX-211 expects to become a cornerstone in the pain management toolkit for cancer patients, enhancing their overall comfort and care.

With the Phase 1 clinical trial complete, the next stage for IRX-211 is to commence the planned Phase 2 Double-blind, Placebo-controlled, Multicenter, Cross-over Study with Titration Period to Evaluate the Efficacy and Safety of IRX211a for the Treatment of Breakthrough Cancer Pain ('**BTcP**') in opioid tolerant patients in order to assess safety and efficacy of IRX-211.

The trial has been strategically designed to mirror the registration trials used for the fentanyl products, which are the only FDA approved drugs for treating BTcP.

The Drug Development Pathway for IRX-616a

IRX-616a is an innovative drug device medication designed to offer fast and effective relief for individuals suffering from panic disorder (‘**PD’**). PD is a debilitating condition characterised by sudden, overwhelming episodes of anxiety and fear, often accompanied by physical symptoms such as shortness of breath, heart palpitations, and chest pain.

IRX-616a is a device-drug combination designed to deliver CBD based medicine quickly and safely into the circulation, ensuring excellent bioavailability and a rapid onset action (i.e. near-immediate relief from acute panic attacks).

Current treatments for PD often have delayed onset of action or can be difficult to administer during an attack. IRX-616a aims to meet this critical need by offering a fast-acting, easy-to-use solution. IRX-616a is therefore well positioned to significantly improve the quality of life for individuals dealing with PD, helping them recover quickly from sudden, distressing attacks.

The Company received feedback from the Bellberry Limited Human Research Ethics Committee (‘**HREC’**) in late 2023 following its Phase 2 HREC application which mandated the requirement to conduct a Phase 1 clinical trial in order to gain additional Pharmacokinetic (‘**PK**’) data on IRX616a. This outcome was not unexpected, and accordingly, the next step will be to conduct a Phase 1 study.

With funding secured, the Company will commence a tender process to select a Clinical Research Organisation (‘**CRO**’) to oversee the Phase 1 Randomized, Double-Blind, Placebo-Controlled Single Ascending Dose Study to Assess the Pharmacokinetics, Safety and Tolerability of CBD Inhalation Aerosol in Healthy Adult Volunteers.

Following completion of the Phase 1 trial, IRX intends to re-apply for HREC approval to conduct its planned Phase 2 trial. In parallel, the Company will also undertake the required non-clinical toxicology studies to become Phase 3 ready.

As part of its strategy to achieve a New Drug Approval (‘**NDA’**), the Company lodged an IND with the FDA on 30 May 2024 for a phase 1 clinical trial of IRX616a. After considering the Company’s detailed submission, the FDA advised of the official temporary suspension (also referred to as a ‘clinical hold’) of the clinical trial specifically outlined in the IND application pending completion of the required standard non-clinical toxicity studies.

Aside from the non-clinical requirements detailed by the FDA, the Company is pleased that other aspects of the IND application (i.e., clinical study design, safety monitoring protocols, investigator qualifications, manufacturing methods and drug specification) appear to have met FDA requirements. The FDA’s targeted feedback therefore provides clarity on where IRX needs to focus its planning and resources. As such, the Company expects to be able to lift the clinical hold upon completion of a small number of non-clinical studies - which will finalise the IRX616a non-clinical testing program.

This combined program is expected to be completed by the end of 2027 and will be fully funded under the Clendon Biotech Capital facility to enable IRX211 to reach Phase 3 ready stage.

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The Company looks forward to updating shareholders on the progress of our trials and the next phase of our clinical journey.

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 and BTcP and 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.

APPENDIX 1 – SUMMARY OF MATERIAL TERMS OF FACILITY AGREEMENT

The terms of the funding agreement include a competitive interest rate of 15% per annum (capitalizing monthly), with repayment terms tied to the completion of each project. Additionally, as part of this funding arrangement, Clendon Biotech Capital will receive options in InhaleRx representing 19.9% of the ordinary shares on issue.

The Company must repay the money owed in cash, but may use the proceeds from the exercise of the Options to make the repayments.

The exercise price of the Options is the higher of:

(a) $0.025 per Option; and

(b) a price equal to 90% of the 90-day volume-weighted average price (**'VWAP'**) of the Shares in the Company ending one business day before the date of exercise of the Option.

The facility will be secured by a General Security Deed granted by the Company in favor of Clendon Biotech Capital over all of its assets and undertaking.

A summary of the key elements of the facility agreement is set out below.

Facility Agreement	**Material Terms**
Lender	Clendon Biotech Capital Ltd (ACN 674 054 267)
Borrower	InhaleRX Limited (ACN 611 845 820)
Facility Limit	The Lender will make available to the Borrower up to $38,475,110 which will be used for clinical trial costs, including the associated non-clinical work and trial drug manufacturing costs in respect of the IRX-211 Facility and the IRX-616a Facility. The Facility comprises an amount up to: (a) $15,487,555 for the IRX-211 Facility; and (b) $16,087,555 for the IRX-616a Facility; and (c) $6,900,00 for capitalised interest.
Drawdown	The Facility may be drawn monthly to meet approved expenditure in respect of each project. Each drawdown is subject to conditions precedent, including conditions customary for a facility of this nature, and: (a) (Default) there being no Default under the Facility Agreement

	(b) (Permitted Purpose) the Lender is satisfied (acting reasonably) that the proceeds of the Drawing will be applied for a Permitted Purpose of that Facility; (c) (Work Product) the Lender being satisfied (acting reasonably) with the conduct and the outcomes of the previous Phases of the development of the inhaled therapeutic under the Project which that Facility is funding; (d) (Costs and Completion) the Lender being satisfied (acting reasonably) that the balance of the development of the inhaled therapeutic under the Project to which the Facility relates will be able to be completed within the agreed timeframe and the agreed budgets; (e) (Phase 3 achievable) the Lender continuing to be satisfied (acting reasonably) that at the completion of the development of the inhaled therapeutic under the Project to which the Facility relates that inhaled therapeutic will be ready for Phase 3 Clinical Trials.
Termination Date	The Termination Date is: (a) For the IRX-211 Facility – the date that is 24 months after the earlier of the first drawdown date with the option at the Lender's sole discretion to extend the termination for another 12 months; and (b) For the IRX-616a Facility – the date that is 30 months after the earlier of the first drawdown date with the option at the Lender's sole discretion to extend the termination for a further 12 months.
Repayment	On the Termination Date, the Borrower must pay the principal outstanding and all other secured moneys owing in full to the Lender.
Mandatory prepayment	The Borrower must apply all: (a) GST recovered by the Borrower in respect of expenses funded by the Facility; and (b) amounts received by the Borrower under, or as an advance in respect of, the Research and Development Tax Incentive program, in part repayment of amounts drawn under the Facility. The Borrower must immediately repay all amounts owing under the Facility if there is a change of control of the Borrower.

Security Documents	A general security deed dated on or about the date of the Facility Agreement and granted by the Borrower in favour of the Lender over all of its assets and undertaking.
Interest	15.00% per annum, capitalised monthly
Options	Subject to shareholder approval, the Borrower will issue the Company with 38,449,145 Options on the terms contained in Schedule 2.
Fees	No establishment fee is payable on the facility.

APPENDIX 2 – SUMMARY OF MATERIAL TERMS OF OPTIONS

Option Terms

(a) Definitions

Capitalised terms used but not defined in these Option Terms have the meanings they have been given in the Facility Agreement.

The following definitions apply in these Option Terms:

Commencement Date	means the date which is the earlier of: (i) the date that the Company notifies Clendon Biotech Capital in writing that it wishes to repay all amounts owing to Clendon Biotech Capital in respect of the Secured Moneys; (ii) 10 Business Days prior to the date on which the repayment of any of the Secured Moneys is due to be paid by the Company to Clendon Biotech Capital; (iii) all of the Secured Moneys are declared by the Lender to be immediately due and payable; (iv) the date on which the Company announces to the ASX that: (A) a takeover bid for the Company's shares has become unconditional; or (B) a scheme of arrangement with respect to the Company has been approved by the Court; and (v) such other date as is agreed in writing by the parties
Exercise Date	means the date the Company receives the Notice of Exercise from to Clendon Biotech Capital.
Exercise Period	means the period commencing on the Commencement Date and expiring on the Expiry Date.
Exercise Price	means the higher of: (i) 0.025 per Option; and (ii) a price equal to 90% of the 90-day volume-weighted average price (VWAP) of the Shares in the Company ending one business day before the date of exercise of an Option,
Expiry Date	means the date which is the earlier of:

	(i) ten Business Days following the Commencement Date; or (ii) 5 years from the date of issue of the Options.
Facility Agreement	means the Facility Agreement entered into between Clendon Biotech Capital (as Lender) and the Company (as Borrower) dated on or about 17 October 2024 to which these Option Terms are attached.
Option	means an option to subscribe for a Share for the Exercise Price.

(b) Entitlement

Each Option entitles the holder to subscribe for one Share upon exercise of the Option.

(c) Subscription price

The Options will be issued for nil consideration.

(d) Exercise Price

The amount payable upon exercise of each Option will be the Exercise Price.

(e) Commencement Date

Each Option is exercisable on and from the Commencement Date.

(f) Expiry Date

Each Option will expire at 5:00 pm (AEDT) on the Expiry Date. An Option not exercised before the Expiry Date will automatically lapse on the Expiry Date.

(g) Exercise Period

(i) Each Option is exercisable during an Exercise Period.

(ii) Subject to paragraph (g)(iii), an Option not exercised during an Exercise Period lapses.

(iii) If the Commencement Date of the Exercise Period is as a result of:

(A) the Facility in respect of IRX 211 maturing and becoming due and payable by the Company to CBC under the Facility Agreement;

(B) a Voluntary Prepayment being made under the Facility Agreement;

(C) the Lender declaring the Secured Moneys to be immediately due and payable; or

(D) a takeover bid becoming unconditional or a scheme of arrangement being approved by the Court that does not result in all of the issued shares in the Company being transferred,

then an Option not exercised during the Exercise Period will not lapse and is capable of being exercised by CBC during a subsequent Exercise Period.

(h) Notice of Exercise

The Options may be exercised during the Exercise Period by notice in writing to the Company in the manner specified by the Company (**Notice of Exercise**) and payment of the Exercise Price for each Option being exercised in Australian currency by electronic funds transfer to the Company or other means of payment acceptable to the Company.

(i) Exercise Restrictions

The number of Options that may be exercised at one time must be not less than 10,000, unless the holder of the Options (**Option Holder**) holds less than 10,000 Options in which case all Options must be exercised at one time.

(j) Exercise Date

A Notice of Exercise is only effective on and from the Exercise Date.

(k) Timing of issue of Shares on exercise

Within 5 Business Days after the Exercise Date, the Company will:

(i) issue the number of Shares required under these terms and conditions in respect of the number of Options specified in the Notice of Exercise and for which cleared funds have been received by the Company;

(ii) if required, give ASX a notice that complies with section 708A(5)(e) of the Corporations Act, or, if the Company is unable to issue such a notice, lodge with ASIC a prospectus prepared in accordance with the Corporations Act and do all such things necessary to satisfy section 708A(11) of the Corporations Act to ensure that an offer for sale of the Shares does not require disclosure to investors; and

(iii) if admitted to the official list of ASX at the time, apply for Official Quotation on ASX of Shares issued pursuant to the exercise of the Options as the case may be.