29 January 2026

ASX Announcement

QUARTERLY ACTIVITIES, CASHFLOW REPORT and OPERATIONS UPDATE

Quarter ended 31 December 2025

InhaleRx Ltd (ASX: IRX), ('**InhaleRx', 'IRX'** 'or '**the Company'**), an Australian drug development company developing novel inhaled and oral medicines, is pleased to provide its quarterly activities, cash flow report and an update of operations.

IRX currently has three drugs under development:

1) IRX-211, an inhaled treatment for breakthrough cancer pain ('**BTcP**'); and
2) IRX-616a, an inhaled treatment for panic disorder ('**PD'**).
3) SRX-25, an oral treatment for treatment-resistant depression ('**TRD**').

The Company's planned clinical trial programs' aim is to demonstrate the safety, tolerability and efficacy for treating a targeted range of pain and mental health 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:

Fundraising activities

- Completion of a Placement which raised $750,000 (before costs) and an Entitlement Offer which raised $107,730 (before costs). These funds will be used to cover operating costs.
- Extension of the Funding Agreement with IRX's funding partner, Linlithgow Family Office Pty Ltd **('LFO'),** by $12.6m (plus capitalised interest charges) to cover the clinical development costs of SRX-25 through to Phase 3 readiness.

IRX-211

- The Company continued engagement with the clinical sites via its appointed Clinical Research Organisation ('**CRO'**), Ingenu CRO Pty Ltd ('**Ingenu'**) for the IRX-211 Phase 2 trial, with a focus on finalising Clinical Trial Research Agreements ('**CTRA'**) with Vitalis (Lead Site), Genesis, and South-West Sydney Health.
- Completion of manufacturing of the trial drugs for the IRX-211 Phase 2 trial, with Ingenu completing the Site Initiation Visit at the lead site.
- Training of site personnel by Ingenu has taken place in preparation for the commencement of patient screening and dosing at Vitalis.

IRX-616

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- Execution of a CTRA between the Company and CMAX has occurred for the IRX-616a Phase 1 trial.
- Manufacturing of the trial drugs for the IRX-616 Phase 1 trial is complete, with Ingenu planning to complete the Site Initiation Visit, Site Activation and Screening at CMAX all in Q1.

SRX-25

- Drafting of the Protocol and Investigator's Brochure ('**IB'**) for SRX-25 has significantly progressed over the quarter, together with planning for the Phase 1 clinical trial.

Clinical development pathway – general update

Activities are progressing well across both the IRX-211 and IRX-616a clinical development programs as the Company prepares for screening and dosing of clinical trial patients. The commencement of patient screening for the IRX-211 Phase 2 trial has been delayed due to difficulties in finalising the site budget (discussed further below).

The Company's core focus for the quarter ending 31 December 2025 was:

1. Monitoring the engagement and progression of negotiations with identified Australian sites by the appointed CRO, Ingenu, with a view to attempting to accelerate patient recruitment and execution of the IRX-211 Phase 2 trial.
2. Ensuring, via engagement with Ingenu, that the lead site in Melbourne for the Phase 2 IRX-211 trial is ready for First Patient In ('**FPI'**). This has been delayed due to site availability and budget negotiations following a series of late changes to the proposed quotes, which have now been resolved and agreed.
3. Manufacturing of the IRX-211 trial drugs; and IRX-616a trial drugs.
4. Timeline and resourcing planning for IRX-616a Phase 1 clinical trial, in consultation with Ingenu and CMAX in Adelaide.
5. Drafting of the Protocol and IB for SRX-25, together with planning for the commencement of the Phase 1 clinical trial.

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 – IRX211 (Phase 2 HREC Approved)

There are currently no non-opioid, inhaled treatments approved by the FDA to treat BTcP. Furthermore, most of 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. The cancer pain market is expected to grow to an estimated Total Addressable Market ('**TAM'**) of USD $10.98b by 2028.

IRX-211 is the more advanced clinical asset within the IRX portfolio with a Phase 2 trial HREC approved to start dosing patients that suffer with BTcP.

To date, over 200 patients have responded to an expression of interest to enrol in the study since the

recruitment process commenced in November. Patients who meet the criteria will be pre-qualified with those found to be eligible invited to be consented in person at the lead site.

The planned design for the ethics approved Phase 2 trial is a double-blind, placebo-controlled, multicenter, crossover study with a 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. At least 78 eligible patients are planned to be randomised and entered into Part B.

The focus for the quarter ending 31 December 2025 for IRX-211 was on the following:

1. Attempting to finalise the site budget and CTRA through negotiation between Ingenu and the lead site (Vitalis).
2. Manufacturing of the second active batch of the trial drug by Ab-Initio Pharma in Sydney in preparation for screening and dosing.
3. Pressing Ingenu for advancement of additional clinical trial sites to speed up the recruitment rates and ultimately close out the Phase 2 trial as quickly and efficiently as possible.
4. Ensuring that Ingenu has completed SIV and Protocol training with site staff.

The Company is reliant on its appointed CRO, Ingenu, for the identification and engagement with potential trial sites. Ingenu, as the Company's agent, is responsible for negotiating the site budgets and CTRA terms, with the Company having limited involvement in this process, beyond final approval of the trial budget and execution of the CTRA.

Delays relating to patient screening experienced during the December quarter arose from factors largely outside the direct control of IRX's management and board, including the need to consider multiple proposals from the site in relation to costs, which have continued into January. While this process resulted in some delays, IRX is pleased to confirm that agreement on the budget with Vitalis has now been reached, and the CTRIA is expected to be signed shortly.

The site budget for Genesis Care's sites was agreed in December, with CTRA execution awaiting the finalisation of internal governance and management processes within the Genesis Care organisation. The CTRA is currently expected to be executed in February, with site initiation and patient screening to commence shortly thereafter.

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

1. Activate the lead site, Vitalis.
2. Finalisation of the CTRA with Genesis Care.
3. Site initiation visit followed by activation at Genesis Care.
4. Finalisation of the CTRA with South West Sydney Health.
5. Site initiation visit followed by activation at South West Sydney Health.

6. Delivery of the Investigational Medicinal Product ('**IMP**'), followed by site activation at the lead site.
7. Screening and dosing in the patient population at the lead site.

Mental health indication – 616a HREC Approved Phase 1

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 it is estimated that the TAM for anxiety disorders and depression treatments will increase to $13.3b USD by 2027.

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.

The focus for the quarter ending 31 December 2025 was on the following:
1. Approving the final budget and execution of the CTRA at CMAX in Adelaide.
2. Monitoring planning of the randomisation schedule and timeline planning for the three cohorts.
3. Completion of the trial drug manufacturing.
4. Planning for the Phase 2 trial that the Company is aiming to commence in quick succession following the completion of the Phase 1 trial.

The next steps in the IRX-616a Phase a clinical trial program are:
1. Site initiation visit and protocol training.
2. Site activation with timeline confirmation
3. Delivery of the trial drug.
4. Screening and dosing of health volunteers currently scheduled to commence in Q1.

New asset added to the pipeline – SRX-25 planning stage

SRX-25 is administered orally and designed to address key limitations in the current treatment landscape for treatment-resistant depression, by combining two well characterised compounds with complementary mechanisms of action.

Esketamine, an NMDA receptor antagonist, has demonstrated rapid antidepressant effects in TRD patients; however, it is currently available primarily as an intranasal formulation that must be administered under medical supervision in a clinical setting. This requirement significantly restricts patient access and introduces logistical, cost and adherence barriers, preventing many eligible patients from receiving treatment.

The unmet need in TRD remains significant, with the global market in 2023 valued at USD $1.95 billion and projected to more than double to USD $4.06 billion by 2030. In the United States alone, approximately 2.8

million patients are affected by TRD, yet only a small proportion can access esketamine therapy due to barriers such as cost, stigma, and the logistical demands of in-clinic administration. By addressing these constraints, SRX-25 has the potential to meaningfully expand treatment access to a large population of patients who currently lack effective and practical therapeutic options.

SRX-25 incorporates an undisclosed CYP45 inhibitor that functions as a pharmacokinetic enhancer, reducing the metabolism of esketamine and allowing a substantially greater proportion of the active compound to reach systemic circulation. This approach enables the opportunity for an oral formulation, with the potential to significantly expand patient access, improve convenience, and support more consistent adherence while preserving the rapid-onset antidepressant effects that underpin esketamine's clinical value.

The Company's development plan includes a Phase 1 pharmacokinetic study, with the medical writing associated with the protocol and IB nearing completion. It is expected that a successful conclusion of the Phase 1 trial will allow commencement shortly thereafter of a Phase 2 proof-of-concept trial, with the goal of achieving Phase 3 readiness for SRX-25 within two to three years of initiating the Phase 1 trial.

Funding agreement update

In October 2024, IRX entered into a funding facility (**the Funding Agreement**) with Clendon Biotech Capital Pty Ltd ('**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.

In October 2025, Clendon requested that IRX execute an assignment deed with a new financier, Linlithgow Family Office Pty Ltd **('LFO')** which had the effect of transferring the Funding Agreement to LFO. There was no material change to the Funding Agreement resulting from this assignment at that time.

InhaleRx subsequently negotiated further funding support from LFO to cover the cost of development of SRX-25. This included funding of approximately $12.6 million (excluding interest capitalised) for the manufacturing, non-clinical work and Phase 1/2 trial costs of the new program, positioning the new asset to be carried through to Phase 3 readiness in as little as 2-3 years from commencement of the Phase 1 trial. The additional funding brought the total commitment under the Facility to approximately $52.3 million. The consideration for the increase in the facility limit is the granting by the Company of an additional 10.9 million options to LFO ("**LFO Options**").

The LFO Options, when added to the existing options held by LFO, in number equate to approximately 19.9% of the total ordinary shares on issue following the Placement, have a vesting window which aligns with the completion of the phase 2 clinical programs for each of IRX-211, IRX-616a and SRX-25. The Company's objective is to ensure that the value of these medications as Phase 3 ready assets is properly reflected in IRX's share price at the time that the options vest such that LFO's exercise of the options at a 10% discount to IRX's 60 Day Volume Weighted Average Price ('VWAP') will generate sufficient proceeds to repay the loan.

The LFO options will be issued subject to shareholder approval at an EGM which is scheduled for 29 January 2026.

Capital management

Placement

The Company completed a capital raise, in the form of a Placement, with commitments to raise $750,000 (before costs) via the issue of approximately 30 million new fully paid ordinary shares in the Company at an offer price of $0.025. The capital raise secures working capital for expenditure that is not eligible under the Funding Agreement.

Participants in the Placement will receive one free attaching investor option for every two shares subscribed (1:2), subject to shareholder approval, exercisable at $0.042 expiring two years from the issue date.

The Placement was structured in two stages, with the first stage seeing the Placement shares up to a total of $600,000 issued pursuant to the Company's placement capacity under ASX Listing Rule 7.1, with the balance of $150,000 (second stage) to be issued subject to shareholder approval, together with the attaching options at the EGM scheduled for 29 January 2026.

Peak Asset Management Pty Ltd ('**Peak'**) was Lead Manager to the Placement.

Entitlement Offer

Following the Placement, the Company issued a non-renounceable entitlement offer ('**Entitlement Offer'**) on the same terms as the Placement – being one (1) new share for every 22 shares held by eligible shareholders. The Company raised $107,730 (before costs) under the Entitlement Offer, with 4,309,185 new ordinary shares and 2,154,603 options issued on 23 December 2025.

The Company has commenced working with the Lead Manager to place the balance shortfall under the Entitlement Offer (5,597,549 shares and attaching 2,798,764 options) within three months of the Closing Date (17 March 2026) at a price not less than the $0.025 Offer Price.

The Company is very grateful to the shareholders that participated in its capital-raising activities and continues to apply a disciplined approach to the incurrence of operational expenditure.

Rebranding to Nexalis Therapeutics Ltd

The Company announced on 26 November 2025, subject to shareholder approval, that it would rebrand as **Nexalis Therapeutics Limited** to accommodate the new oral asset and be reclassified as a drug development company.

This rebrand is considered a necessary course of action with the Company no longer specialising solely in the development of inhaled therapies. The proposed company name of Nexalis Therapeutics Limited has been reserved with ASIC and a new ticker of **NX1** reserved with ASX.

All preparations for the rebrand are now in place pending the approval of shareholders at the EGM on 29 January 2026.

Payments to Directors & Related Parties

There were no cash payments to Directors during the December 2025 quarter. All current year Director entitlements are to be paid in the form of performance rights as per the shareholder approval at the May 2025 Annual General Meeting.

$19k in salaries were paid to Key Management Personnel.

Use of funds

The net cash outflow from operating activities during the quarter was $628k.

The Company incurred $485k in clinical development costs for the December 2026 quarter and received $405k of funding under the Funding Agreement with Clendon/LFO. The Company has now completed a reconciliation of all amounts due to be transferred to LFO related to its 2024 income tax return in respect of invoices claimed in that year which were subsequently credited and re-issued by Ingenu in 2025 under the current IRX-211 study order. The reconciliation also considered some costs paid directly by IRX earlier in the year that were covered by the Funding Agreement. The balance of $80k in clinical development costs funded by IRX in the quarter was accounted for within the reconciliation.

$369k of forward Research & Development Tax Incentive ('**RDTI'**) funding was received from Radium Capital during the quarter and this was used to repay the Funding Agreement debt. The Radium Capital facility will be repaid from the proceeds of the Company's 2025 RDTI claim.

During the quarter, funds spent on operating activities comprised:

- $485k in clinical development costs;
- $110k in general corporate costs, including insurance ($60k); tax and audit ($14k); CFO ($13k); company secretary ($12k); share registry & ASX ($5k); legal ($3k) and capital raise costs ($3k);
- $23k in investor relations costs; and
- $19k in salaries paid to employees.

The Company received ATO net refunds totaling $9k related to GST during the quarter.

GST is included in the amounts noted above as applicable.

The Company will provide further updates at a TownHall meeting planned for 12th February 2026 at 2pm AEDT.

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 and oral therapies to address unmet medical needs in the pain management and mental health sectors. The Company has secured a funding facility of up to $52.3m to accelerate the development of IRX-211 to treat breakthrough cancer pain ('**BTcP'**), IRX-616a to treat panic disorder ('PD') and SRX-25 to treat treatment resistant depression ('**TRD'**).

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 and other limitations in treatment.

References

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Anxiety reference – 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

TRD reference - Treatment-Resistant Depression Treatment Market Size [2030]

The Prevalence and National Burden of Treatment-Resistant Depression and Major Depressive Disorder in the United States - PubMed