InhaleRx Bolsters Drug Development Pipeline with Ketamine-based oral-fixed dose drug Asset SRX-25, Targeting Blockbuster Depression Indication

Highlights:

- **InhaleRx has added a new fixed-dose combination (FDC) therapy to its drug development pipeline, combining Esketamine and CYP450 inhibitor (accelerator) to address a significant unmet need in Treatment-Resistant Depression (TRD).**
- **SRX-25 oral formulation has similarities to intranasal Esketamine product Spravato, manufactured by Johnson and Johnson. The oral pharmacokinetics intend to improve adherence, convenience and treatment.**
- **The global TRD market was valued at USD $1.95 billion in 2023 and is projected to grow to USD $4.06 billion by 2030[1].**
- **Development will proceed via the 505(b)(2) regulatory pathway, leveraging existing safety data to accelerate timelines and reduce cost.**
- **The study design provides for a Phase 1 pharmacokinetic study and a Phase 2 proof-of-concept trial to position SRX-25 for rapid Phase 3 readiness.**
- **The manufacturing, non-clinical work and Phase 1/2 trial costs of the SRX-25 program will also be covered by the Company's clinical development facility with the Linlithgow Family Office.**
- **The Company completed a Placement of shares at 2.5 cents, raising up to approximately $750,000 before costs. IRX will also undertake a Non-Renounceable Rights Issue Offer on the same terms as the Placement to eligible shareholders to raise up to $250,000 before costs.**
- **Leading Melbourne boutique, Peak Asset Management, acted as Lead Manager to the Offers.**

Melbourne, Australia – 26 November 2025 – InhaleRx Ltd ("**InhaleRx**" or "**the Company**") is pleased to announce plans to add new asset SRX-25 to its clinical development pipeline, an oral fixed-dose combination ("**FDC**") therapy that combines Esketamine and CYP450 inhibitor (accelerator) for the treatment of Treatment-Resistant Depression ("**TRD**") – a major global mental health burden.

SRX-25 has been designed to address significant gaps in the current TRD treatment landscape by pairing two well-characterised compounds with complementary mechanisms. Esketamine, a known NMDA receptor antagonist, has demonstrated rapid antidepressant effects in TRD patients, but is currently available predominantly as an intranasal formulation (Spravato, marketed by Johnson & Johnson) which must be administered under medical supervision in a clinical setting. This requirement limits patient access and creates logistical, cost, and adherence challenges that prevent the majority of eligible patients from receiving therapy.

The undisclosed CYP45 inhibitor acts as a pharmacokinetic enhancer by reducing the metabolism of esketamine and enabling a substantially greater proportion of the active compound to reach systemic circulation. This enhancement makes an oral formulation viable, realising its potential for broader patient accessibility, improved convenience, and more consistent adherence – without compromising the rapid-onset antidepressant effect that underpins esketamine's clinical utility.

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SRX-25's oral formulation is intended to leverage Spravato's pharmacokinetic profile while offering a significantly more scalable, patient-centric mode of administration. This approach directly addresses the major barriers that currently prevent widespread adoption of intranasal Esketamine. While Spravato has proven efficacy, its delivery method remains a key limitation, requiring extended clinic visits, supervision periods, and infrastructure not widely available across mental-health treatment settings.

The unmet need in TRD is substantial with a global market valued at USD $1.95 billion in 2023, projected to more than double to USD $4.06 billion by 2030[1]. In the United States alone, an estimated 2.8 million patients suffer from TRD[2], yet only a fraction access Esketamine due to issues including cost, stigma, and the burdens associated with in-clinic administration. SRX-25 aims to directly address these challenges, potentially expanding treatment reach to the vast proportion of patients currently left without effective or practical options.

Development of SRX-25 will proceed via the US FDA's 505(b)(2) regulatory pathway, allowing the Company to leverage extensive existing safety data associated with the individual components. This pathway is designed to reduce development timelines and cost, while being well aligned with InhaleRx's focus on capital-efficient advancement of novel therapeutic programs.

The Company's development plan provides for a Phase 1 pharmacokinetic ("**PK**") study followed by a Phase 2 proof-of-concept trial, with the objective of positioning SRX-25 for Phase 3 readiness within two to three years of commencement of the Phase 1 clinical trial. In parallel, InhaleRx will prepare and lodge patent filings to protect the formulation and associated methods of use. As the program matures, the Company intends to pursue multiple value-creation pathways, including potential licensing, asset sale, or co-development partnerships for Phase 3 and beyond.

InhaleRx has received further support from its existing funding partner, the Linlithgow Family Office (**LFO**), for development of SRX-25. This will include additional 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. The termination dates of the loans for each Phase of the SRX-25 funding are 7 months and 13 months from first drawdown of that loan (as applicable). All other terms of the SRX-25 loans are the same as original Facility. The additional funding brings 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**") on the same terms as the options previously issued in respect of the Facility.

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 90 Day Volume Weighted Average Price ('VWAP') will generate sufficient proceeds to repay the loan.

InhaleRx CEO Darry Davies said: "Treatment-Resistant Depression remains a pressing challenge in psychiatric medicine. Approximately 30% of patients with major depressive disorders do not respond adequately to first-line therapies, leading to a TRD diagnosis and leaving clinicians with limited accessible

options. By bringing to market oral administration of Esketamine in a clinically meaningful manner, we have the potential to bring a major step-change in how TRD can be treated at scale."

Subject to shareholder approval, the Company proposes to rebrand as **Nexalis Therapeutics Limited** to accommodate the new oral asset and to 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.

The creation of SRX-25 marks a strategic expansion of InhaleRx's mental-health development portfolio and reinforces the Company's commitment to advancing differentiated therapies that address major unmet medical needs.

Capital Raising

The Company is also pleased to announce it has received firm commitments for a Placement 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 Placement of shares at $0.025 (2.5 cents) represents a discount of 30.6% to the closing price as at 21 November 2025 and a discount of 19.0% to the 30-day VWAP.

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.

Placement shares up to a total of $675,000 will be issued pursuant to the Company's existing placement capacity under ASX Listing Rule 7.1, with the balance of $75,000 to be issued subject to shareholder approval, together with the attaching options.

Peak Asset Management was Lead Manager to the Placement.

Rights Issue

Following the Placement, the Company intends to undertake a non-renounceable rights issue on the same terms as the Placement – being one (1) new share for every 22 shares held by eligible shareholders in Australia and New Zealand at an offer price of $0.025 (2.5 cents) per new share plus 1 option for every 2 new shares issued under the rights issue offer (**New Options**), to raise up to approximately $250,000 (before costs) by the issue of up to 9,906,734 new ordinary shares (**Rights Issue Offer**).

Shareholders who subscribe for their full entitlement under the Rights Issue Offer can also apply for Shortfall Securities in excess of their Entitlement under the Shortfall Offer. There is no guarantee that Eligible Shareholders will be allocated any Shortfall Securities under the Shortfall Offer. Shares issued under the Shortfall Offer will also be issued 1 new option for every 2 additional shares issued to them under the Shortfall Offer.

Similar to the Placement Options, the New Options will have an exercise price of $0.042 (4.2 cents) and will expire 2 years from issue.

Peak Asset Management will also act as Lead Manager of any shortfall available at the conclusion of the Rights Issue.

Issues under this Rights Issue Offer will be made pursuant to a prospectus to be issued in accordance with Section 713 of the Corporations Act and therefore the Rights Issue Offer will not affect the Company's current Listing Rule 7.1 capacity.

No shareholder approval is required for the Rights Issue Offer. The new shares will be fully paid ordinary shares, will rank equally with the Company's existing issued shares and the Company will make an application to the ASX for the official quotation of the new shares.

The Directors also reserve the right for up to 3 months after the close of the Rights Issue Offer to place the balance of any new shares (and accompanying options) not taken up.

Further information pertaining to the Rights Issue Offer will be sent to eligible shareholders in a Prospectus to be lodged with ASIC and the ASX.

Use of funds

Funds from the capital raising activities will be deployed to non-clinical working capital and costs of the Offers.

Timetable

The following is an indicative timetable for the Rights Issue Offer:

Event	**Date***
Announcement of Entitlement Offer	26 November 2025
Lodgement of Prospectus with ASIC Lodgement of Prospectus with ASX	27 November 2025
"Ex Date"	1 December 2025
Record Date	2 December 2025
Offer Documents are sent to Shareholders Offer opening date is at 9:00 am	5 December 2025
Offer Closing Date as at 5:00 pm**	17 December 2025
Company announces results of the Entitlement Offer Issue of New Shares and New Options Lodgement of Appendix 2A with ASX	23 December 2025
Anticipated date for dispatch of holding statements for New Securities	24 December 2025
General Meeting of Company	21 January 2026
Issue of New Shares and Options approved at the General Meeting	23 January 2026

Dates / times are indicative and subject to change. All times / dates are in reference to Australian Eastern Standard Time

Authorised by the Board of Directors.

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[1] https://www.fortunebusinessinsights.com/treatment-resistant-depression-treatment-market-102820
[2] https://pubmed.ncbi.nlm.nih.gov/33989464/

About InhaleRx Limited (ASX: IRX) – www.inhalerx.com.au

InhaleRx Limited is an Australian Clinical Stage Drug Development Company that is developing rapid onset, inhaled therapies to address unmet medical needs in pain management and mental health sectors. The Company has secured a funding partner with a 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 for the treatment of 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 IRX and the Company's shareholders, the clinical indications under investigation have been carefully selected in consultation with regulatory authorities. Bringing new approved medications to market will address critical gaps whereby there's currently mismatched treatment options that can carry dependency concerns.