



30 April 2024

ASX Announcement
QUARTERLY ACTIVITIES, CASHFLOW REPORT and OPERATIONS UPDATE
Quarter ended 31 March 2024

InhaleRx Ltd (ASX: IRX), (**InhaleRx**, **IRX** or **the Company**) an Australian healthcare company developing unique inhaled medicinal drug-device products to address unmet medical needs in pain management and mental health sectors, is pleased to provide its quarterly activities, cash flow report and an update of operations.

Operational highlights are as follows:

- Cash reserves at 31 March 2024: \$465k.
- Net cash used in the quarter for operating activities: (\$430k).
- The database was locked in early February for the IRX211 Phase 1 clinical trial with no serious adverse events and the Company is now awaiting the Clinical Study Report (**CSR**) from Ingenu CRO Pty Ltd (**Ingenu**) as the Contract Research Organisation (**CRO**) which is anticipated in Q2 2024.
- The Company is in the final stages of preparing for an application with a Human Research Ethics Committee (**HREC**) for Phase 2 trial to investigate the safety and efficacy of IRX211 with patients who have a Breakthrough Cancer Pain (**BTcP**) diagnosis.
- The Company has completed Food and Drug Administration (**FDA**) Pre- Investigational New Drug (**IND**) meetings for both IRX616a and IRX211 indications, a significant amount of work has been completed in the preparation of an IND submission for IRX616a and it is expected to lodge with the FDA in Q2 2024 following some final checks.
- The Company is currently preparing the necessary information for a Phase 1 HREC submission for IRX616a following some valuable insights from the Phase 2 HREC application that was lodged in Q4 2023. The Board of Directors and management team remain confident that IRX will be able to demonstrate the safety and tolerability of inhaled Cannabidiol (**CBD**), which is already licenced for the treatment of rare pediatric-onset epilepsies and widely available as a non-prescription health supplement globally.
- IRX's strategy is to leverage the benefits of three year data exclusivity available for a New Drug Application (**NDA**) under the FDA's 505b(2) pathway. In parallel, the Company has an innovation patent approved (No 2021101157) patent acquired in July 2022, and continues to lodge provisional patent applications.
- The Company entered into a Loan Agreement with Peak Asset Management on 27 March 2024 with \$250k available immediately and a further \$250k draw down available in September 2024. \$190k of the \$250k was received prior to the end of the March quarter.
- The Company has lodged its 2023 income tax return and expects to receive a refund (inclusive of the R&D tax incentive) of \$763k. This will be applied to the repayment of the \$546k received from the Radium Capital finance facility, with \$184k expected to be available to the Company after the payment of interest and fees.

The net cash outflow from operating activities during the quarter was \$430k, with the Company incurring \$175k of one-off research and development expenditure in relation to its IRX211 Phase 1 clinical trial and the HREC submission for the Phase 2 clinical trial of IRX616a.

On 27 March 2024, the Company entered into a \$500k loan agreement with Peak Asset Management. The key terms of the loan are:

- \$250k was payable upon execution, with balance payable six months after the initial disbursement;
- the debt carries an interest rate of 10% per annum, accruing from the date of disbursement or drawdown, to be capitalised, with repayment at completion of the loan term;
- the loan has a 2 year term from the initial disbursement, but may be repaid earlier at the Company's election;
- at any point during the term of the loan, the lender shall have the option to convert any portion of the outstanding principal and accrued interest into ordinary shares of the Company at a conversion price of \$0.05 per share or the 30 day VWAP, whichever is the lower; and
- the lender will also be issued options to purchase ordinary shares of InhaleRx. The number of options issued will be equal to the number of ordinary shares into which the loan is convertible at the conversion price. The options will have an exercise price of \$0.05 per ordinary share and will be exercisable for a period co-terminus with the loan term.

\$190k was received before the end of the March 2024 quarter.

The Company continues to apply a disciplined approach to the incurrence of operational expenditure.

Clinical development pathway - general up-date

The Company's core focus for the March 2024 quarter was on:

1. Database lock for the Phase 1 IRX211 clinical trial.
2. Preparing the IRX211 Phase 2 HREC application.
3. Preparing the Phase 1 HREC application for IRX616a.
4. Completing regulatory work in preparation for the filing of an IND application with the FDA for IRX616a (expected to be lodged in Q2 2024).

The Company's overarching goal remains to achieve a New Drug Application ('NDA') with the FDA. IRX is committed to driving cost efficiency while delivering outcomes in the shortest time frame possible.

Pain Indication

IRX211 clinical trial program update targeting Breakthrough Cancer Pain

The Phase 1 clinical trial has been completed for IRX211 with some very promising efficiency insights and the Company is preparing for the commencement of the Phase 2 trial. The clinical trial protocol has been updated to reflect the BTcP indication, together with the Investigator's Brochure ('IB').

The CSR is anticipated to be available in Q2 2024, with the primary focus for the quarter being on preparing for the Phase 2 HREC application for the Phase 2 clinical trial. A Key Opinion Leader has reviewed the protocol in anticipation of a HREC submission in Q2 2024. A Study Start Up agreement has also been drafted with Ingenu so that the clinical trial site can make an application through to HREC.

Mental health indication

IRX616a clinical trial program update targeting Panic Disorder.

Clinical Trial

The IB and clinical trial protocol have been finalised. A submission was made to Bellberry as the nominated HREC for the Phase 2 trial. The Company received some valuable insights from the initial HREC feedback on its submission and will be conducting a Phase 1 clinical trial before submitting a further Phase 2 HREC application.

Preparations continue for a HREC submission for the Phase 1 clinical trial and the Company is working towards selecting a CRO partner, clinical trial site and principle investigator to submit an application to HREC. A tender is currently being prepared for the purposes of the CRO selection process.

Regulatory

The Company's recent focus has also been on the refinement of an IND submission for IRX616a, which is anticipated to be lodged in Q2 2024.

Capital requirements

The Company's Board resolved to enter into a \$500,000 Convertible Loan Facility (Facility) with Peak Asset Management ('Peak'), with the first drawdown available in Q1 2024, while the remaining drawdown is scheduled to take place in Q3 2024.

The Company continues to develop its plans for raising additional capital in order to execute on its clinical development programs within the anxiety and pain.

The Company is working closely with nominated partners to lodge to HREC applications for both IRX211 Phase 2, and IRX616 Phase 1, with the intent of having ethics approvals in place so that the management team is ready to commence the clinical trials, subject to raising further capital.

Payments to Directors & Related Parties

Cash payments to Directors during the March 2024 quarter totaled \$63k (including GST) with a further \$58k (including GST) paid as salaries to key personnel and contractors.

Use of funds

The Company received \$190k through entering into a loan agreement with Peak Asset Management. There was also an ATO net refund received of \$12k related to GST.

During the quarter, funds spent on operating activities comprised:

- \$175k in clinical development costs (including CRO payments, medical writing, regulatory engagement and trial drug manufacturing);

- \$87k in general corporate costs including CEO (\$28k); company secretary (\$16k); insurance (\$14k); CFO (\$13k); IP/legal (\$9k); and share registry/ASX/ASIC costs (\$7k);
- \$82k in salaries paid to employees;
- \$63k in director fees; and
- \$44k in investor relations/marketing costs.

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.

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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.