31 October 2023

ASX Announcement

QUARTERLY ACTIVITIES, CASHFLOW REPORT and OPERATIONS UPDATE

Quarter ended 30 September 2023

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 30 September 2023: $410k.
- Net cash used in the quarter for operating activities: ($115k).
- The Company received $441k in relation to its R&D tax incentive claim for the 2022 year.
- Formulation and all Good Manufacturing Practice ("**GMP**") manufacturing work has been completed for Phase 1, drug candidates IRX211.
- Formulation work is also complete for IRX616a in preparation to commence Phase 2 clinical trials.
- The Company has completed the US Food & Drug Administration ("**FDA**") pre-Investigational New Drug ("**Pre-IND**") meetings for each indication and a significant amount of work has gone into preparing IND submissions for each. The submission for IRX616a is now close to completion and in progress for IRX211.
- Ingenu CRO Pty Ltd ("**Ingenu**") as the Contract Research Organisation ("**CRO**") is coordinating the completion of dosing of the remaining cohorts for the IRX211 Phase 1 clinical trial. The first cohort was completed on 14 June 2023, with the second cohort completed on 12 September 2023. The Company is planning to have the dosing of cohorts 3 and 4 completed by the end of November 2023.
- The submission to Human Research Ethics Committee ("**HREC**") for the Phase 2 IRX616a clinical trial programme was lodged on 13 October 2023. A Clinical Trial Notification ("**CTN**") has been assigned. The commencement of screening for the Phase 2 clinical trials for each drug-device candidate will, however, be subject to further capital raising.
- IRX's Intellectual Property **("IP")** strategy is ongoing. The Company has both an innovation patent approved and a provisional patent lodged for its pain drug-device combination. In consultation with its patent attorneys, the Company has also drafted a series of provisional patent applications, which are ready to lodge in the lead up to the Phase 2 clinical trial commencement.
- The Board of Directors is very pleased with the pharmacokinetic data observed to date through the phase 1 clinical trial for IRX211, with efficiency surpassing expectations. There are also some unique properties associated with the way the drug device has performed which may provide IRX with the opportunity to develop further novel IP. These opportunities are in the process of being explored in consultation with IRX's patent attorneys.

The net cash outflow from operating activities during the quarter was $115k, with the Company incurring $259k of research and development expenditure in relation to its IRX211 clinical trial. $441k was received in relation to the Company's R&D tax incentive claim for the 2022 year. 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 September 2023 quarter was on:

1. progressing the cohort dosing for the Phase 1 IRX211 clinical trial programme;
2. the preparation of the HREC application for the IRX616a Phase 2 clinical trials; and
3. conducting regulatory work in preparation for the filing of an IND application with the FDA for IRX616a.

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. Considering these priorities, it is vital that the Company carefully considers all regulatory feedback and remains open to making changes across the programmes to increase the probability of improved outcomes for the Company and its shareholders.

The IRX211 phase 1 clinical trial remains a critical cornerstone for all potential future pain indications that are being evaluated by the Company.

Capital requirements: The Board reviews its capital management requirements as a standing agenda item in monthly board meetings. With upcoming strategic priorities, including to execute on its phase 2 clinical trial plans within the anxiety and pain programmes, the Board is assessing several alternative capital management opportunities to raise additional capital, including equity funding. The Company is confident it will be successful in raising additional capital to fund the commencement of Phase 2 clinical trial activities for IRX616 and other value accretive projects.

Manufacturing: Trial batch contract manufacturing has been completed for IRX211 phase 1.

A significant deposit has been paid across both Phase 2 trials and all components, including HFA134a gas, has been sourced and allocated for IRX616a and IRX211. Commencement of manufacturing of the requisite IRX616a drug-device combination will need to be considered once IRX has obtained HREC approval and further capital has been raised to fund these activities.

Mental health indications

IRX616a clinical trial program update targeting anxiety

Drug-Device: IRX has completed the required formulation work, the tech transfer has been completed and all device componentry and HFA-134a gas has been procured and allocated awaiting authorisation to proceed with manufacturing.

Clinical Trial: The Investigator's Brochure ("**IB**") and the clinical trial protocol have been finalised. subject to HREC approval.

Regulatory: IRX continues to work towards the goal of achieving a NDA with the FDA via the FDA 505(b)(2) pathway. The Pre-IND meeting with the FDA was held on 20 October 2022. The Company's recent focus has also been on the preparation of an Investigational New Drug ("**IND**") submission for IRX616a.

Pain indications

IRX211 clinical trial programme targeting pain

Drug-Device: IRX has completed the required formulation and manufacturing work for IRX211. All device componentry and HFA-134a gas for the Phase 2 has been procured and allocated awaiting authorisation to proceed with manufacturing.

Clinical Trials: The clinical trial protocol and the IB have both been finalised. Two of four Phase 1 cohorts are complete with 16 participants dosed. Dosing of the third and fourth cohorts is expected to be closed out before the end of November.

Regulatory: The Pre-IND meeting was held with the FDA on 30 March 2023 to obtain formal FDA feedback in relation to the Company's clinical development plans.

The Company has narrowed the possible pain indications to a few options and intends to pursue an indication that presents as the most cost effective and time efficient route to an NDA, whilst also providing an attractive opportunity on a commercial basis. It is expected that a final decision will be made after the data from the Phase 1 IRX211 clinical trial is available.

Payments to Directors & Related Parties

Cash payments to Directors during the quarter totaled $85k (including GST) with a further $68k (including GST) paid as salaries to key management personnel. $259k(including GST) was also paid to Ingenu in relation to the phase 1 IRX211 clinical trials. Ingenu is a subsidiary of substantial IRX shareholder, Cannvalate Pty Ltd.

Use of funds

The Company received $441k in relation to its R&D tax incentive claim for the 2022 year. There was also an ATO net refund received of $44k related to GST.

During the quarter, funds spent on operating activities comprised:

- $259k in clinical development costs (including medical writing, regulatory engagement and trial drug manufacturing);
- $4k in advertising and marketing;
- $85k in director fees;
- $26k in salaries paid to employees;
- $144k in general corporate costs including insurance ($57k); CEO ($41k); company secretary ($29k); CFO ($13k) and other costs ($4k); and
- $82k in tax/R&D claim advice ($37k); share registry/ASX/ASIC costs ($31k) and IP related legal costs ($14k).

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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