28 April 2023

ASX Announcement

QUARTERLY ACTIVITIES, CASHFLOW REPORT and OPERATIONS UPDATE

Quarter ended 31 March 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 31 March 2023: $1,450k.
- Net cash used in the quarter for operating activities: ($676k).
- Formulation work has been completed for drug candidates IRX616a and IRX211.
- All drug-device Good Manufacturing Practice ("**GMP**") components have been sourced and are with the nominated manufacturer in preparation for trial batch manufacturing.
- The tech transfer was completed during March 2023 from the UK based drug formulation specialist to the Australian GMP trial batch manufacturer, which has been formally engaged to commence manufacturing for both programmes.
- The US Food & Drug Administration ("**FDA**") pre-Investigational New Drug ("**Pre-IND**") meeting for the Complex Regional Pain Syndrome ("**CRPS**") programme occurred on 30 March 2023. The formal feedback from the FDA is expected on 30 April 2023. The FDA was generally supportive of the Company's plans, however, some of the feedback has presented the Company with an opportunity to consider alternative acute pain indications that may provide a more cost effective and time efficient route to a New Drug Approval ("**NDA**").
- The Company intends to progress its planned Phase 1 clinical trial for IRX211 without further delay as this trial is a cornerstone for all future acute pain indications (including CRPS). Ethics Approval for the Phase 1 was granted on 17 March 2023 and First Patient First Dose ("**FPFD**") is expected in the coming months.
- Work has commenced with Ingenu CRO Pty Ltd ("**Ingenu**") as the Contract Research Organisation ("**CRO**") in planning for the commencement of the clinical trial programmes for IRX616a and IRX211. The commencement of the Phase 2 clinical trials for each drug-device candidate will, however, be subject to further capital raising.

The net cash outflow from operating activities during the quarter was $676k, with the Company incurring $456k of research and development expenditure in relation to drug formulation, trial drug manufacturing and regulatory advice in preparation for its planned IRX616a and IRX211 clinical trials. The Company continues to apply a disciplined approach to the incurrence of operational expenditure.

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Clinical development pathway - general up-date

The Company's core focus for the March 2023 quarter was on planning for the financial, regulatory and clinical considerations of its clinical trial programmes.

The Company's overarching goal remains to achieve an NDA with the FDA. IRX is committed to driving cost efficiencies 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.

Following the recent Pre-IND meeting on 30 March 2023 with the FDA for CRPS, the Company has decided to broaden its investigation of potential pain indications suitable for treatment with IRX211. While CRPS continues to be a strong opportunity, some of the FDA feedback has opened the possibility that the use of IRX211 in a range of other acute pain indications may provide a more cost effective and time efficient route to an NDA.

Importantly, the review of pain indications does not affect the importance of the proposed IRX211 phase 1 clinical trial, with this trial forming a critical cornerstone for all potential future pain indications.

Manufacturing: Trial batch contract manufacturing has commenced with the tech transfer completed during March 2023 across both programmes in preparation of the IRX616a and IRX211 development. Manufacturing has commenced in anticipation of the Phase 1 clinical trials for IRX211, with the placebo and 0.5mg dose manufacturing now complete.

Contract Research Organisation (CRO): On 17 February 2023, shareholders at an Extraordinary General Meeting of the Company approved the appointment of Ingenu as the nominated CRO to coordinate the IRX616a and IRX211 clinical trials. This followed a formal tender process.

Ingenu is considered a related party of the Company with shareholder approval being required under ASX Listing Rule 10.1.

IRX management is now working closely with the Ingenu team on detailed clinical trial planning, including obtaining Ethics Approvals, site selection and patient recruitment priorities.

Mental health indications

IRX616a clinical trial programme update targeting anxiety

Drug-Device: IRX has completed the required formulation work, with all device componentry procured and delivered to the manufacturing site in Sydney in preparation for assembly. Tech transfer has been completed and ongoing stability testing continues.

Clinical Trial: The investigator's brochure ("**IB**") and the clinical trial protocol have been finalised. Preparations for the commencement of the Phase 2 (proof-of-concept) trial are on track with the first patient recruited anticipated for the June 2023 quarter, subject to sufficient funding arrangements being in place.

Regulatory: IRX continues to work towards the goal of achieving an NDA with the FDA via the FDA 505(b)(2) pathway. The Pre-IND meeting with the FDA was held on 20 October 2022. An Investigational New Drug ("**IND**") (163026) has been allocated and the Company is satisfied with the defined endpoints and the general trial design to measure the safety and efficacy on Panic Disorder ("**PD"**) in the Phase 2 trials.

Pain indications

IRX211 clinical trial programme targeting pain

Regulatory: As discussed above, a Pre-IND meeting was held with the FDA on 30 March 2023 in order to obtain formal FDA feedback in relation to the Company's clinical development plans for IRX211 as a treatment for CRPS. The formal minutes of the meeting are expected on 30 April 2023.

Whilst overall the FDA feedback was supportive of the Company's plans for CRPS, some of the FDA comments have encouraged the Company to evaluate other pain indications that may be better suited to the IRX211 formulation on that the basis that they may provide a more cost effective and time efficient route to an NDA when compared to CRPS.

A further up-date will be provided once the Company has received the formal minutes from the FDA and completed its detailed assessment of all potential acute pain treatment opportunities.

Whilst the Company is investigating its options for applicable future pain indications, it has decided to progress the Phase 1 clinical trial of IRX211 (safety and efficacy in healthy volunteer clinical trial) as this trial forms a critical cornerstone for all possible pain indications that the Company may choose to investigate in the future. It is considered industry best practice to remain nimble and open to alternative avenues while the Phase 1 clinical trial is conducted, however, the Company recognises that the nominated pain indication will need to be assigned prior to the Phase 2 clinical trial ethics application.

The Company has sufficient funding in place to commence the Phase 1 trial and initiation of this trial is not contingent on future capital raising.

Drug-Device: IRX has completed the required formulation work, with all solubility and spray characteristics have now been determined. The individual pMDI device componentry has been procured and delivered to the manufacturing site in Sydney. Manufacturing has commenced in anticipation of the Phase 1 trial, with manufacturing of the placebo for IRX211 and 0.5mg dose now completed.

Clinical Trials: The clinical trial protocol and the IB have both been finalised. Preparations for the commencement of the Phase 1 trial is on track with Ethics Approval received on 17 March 2023 and FPFD is anticipated in the coming months.

Licences

The Company has obtained the 2023 import/export licences with the Office of Drug Control ("**ODC**") to enable procurement of the medicinal cannabinoid Active Pharmaceutical Ingredients ("**APIs**") for use in upcoming clinical trial programmes.

The Company also has the relevant 2023 Victorian State licences from the Department of Health to supply scheduled substances, including cannabinoids.

Medihale

Trials of Medihale 2.0 continued during the March 2023 quarter. The review of supply chain options also continued and has now been extended to also cover route to market requirements.

Payments to Directors & Related Parties

Cash payments to Directors during the quarter totaled $23k.

Use of funds

During the quarter, funds spent on operating activities comprised:

- $456k in clinical development costs (including medical writing, regulatory engagement and trial drug manufacturing);
- $23k in director fees;
- $22k in salaries paid to employees;
- $117k in R&D tax ($36k), audit related costs ($27k), expert report ($22k), company secretary ($13k), legal ($9k) and share registry/ASX/ASIC costs ($10k); and
- $78k in general corporate costs including CEO ($41k); CFO ($13k) insurance ($7k); and other costs ($17k).

There was also an ATO refund received of $19k.

The Company will provide further updates in due course.

Authorised by the Board of Directors.

For further information:
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