16 January 2024

ASX Announcement

QUARTERLY ACTIVITIES, CASHFLOW REPORT and OPERATIONS UPDATE

Quarter ended 31 December 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 December 2023: $714k.
- Net cash used in the quarter for operating activities: ($242k).
- The Company received $546k through entering into a financing facility with Radium Capital which allowed early access to a part of the R&D tax incentive claim for the 2023 year.
- Dosing for the IRX211 Phase 1 clinical trial was completed in Q4 2023. The Company is now awaiting confirmation from Ingenu CRO Pty Ltd (‘**Ingenu**’) as the Contract Research Organisation (‘**CRO**’) overseeing the clinical trial of database lock and completion of the Clinical Study Report (‘**CSR**’), which are expected over the coming months.
- Following pre-Investigational New Drug (‘**Pre-IND**’) meeting feedback from the US Food & Drug Administration (‘**FDA’**) in March 2023, the Company undertook a detailed and careful evaluation process which has resulted in the decision to promote Breakthrough Cancer Pain (**‘BTcP’**) as the primary indication of focus for the proposed Phase 2 trial of IRX211.
- After careful consideration the Company has decided to prioritise the advancement of the Phase 2 clinical trials for IRX211 ahead of its IRX616a clinical programme, with the encouraging Phase 1 clinical data a key determinant of this decision.
- In light of this refocus, the Company plans to make a submission to Human Research Ethics Committee (‘**HREC**’) for the Phase 2 clinical trials for IRX211 in Q1 2024.
- IRX’s Intellectual Property (‘**IP’**) strategy is ongoing. The Company lodged a provisional patent covering its BTcP drug-device combination in Q4 2023.
- The Company has completed FDA Pre-IND meetings for each indication and a significant amount of work has been completed in the preparation of an IND submission for IRX616a, which we expect to lodge with the FDA in Q1.
- The HREC submission for the Phase 2 clinical trial for IRX616a was lodged in Q4 2023, with the Company receiving some valuable insights from HREC feedback. The Company is currently preparing the necessary information for a resubmission in the coming months.

The net cash outflow from operating activities during the quarter was $242k, with the Company incurring $34k of 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.

$546k was received through entering into a financing facility with Radium Capital which allowed early access to a part of the R&D tax incentive claim for the 2023 year.

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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 December 2023 quarter was on:

1. Finalising the dosing for the Phase 1 IRX211 clinical trial programme;
2. Finalising the review of potential pain indications which resulted in the decision to promote BTcP as the primary indication of focus for the proposed Phase 2 clinical trial of IRX211;
3. Lodgement of the HREC application for IRX616a on 13 October 2023;
4. Preparation of the HREC application for the IRX211 Phase 2 clinical trial; and
5. Completing regulatory work in preparation for the filing of an IND application with the FDA for IRX616a (expected to be lodged in Q1 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.

Capital requirements

The Company has continued to develop its plans for raising additional capital in order to execute on its phase 2 clinical trial plans within the anxiety and pain programmes.

The Company plans to raise capital in the coming months to fund the commencement of Phase 2 clinical trial activities for IRX211.

The Phase 2 clinical trials for IRX616a Company are expected to commence later in this calendar year, subject to a successful further capital raising.

Manufacturing

All requisite components, including HFA134a gas, have been sourced and allocated for IRX616a and IRX211. Commencement of manufacturing of the requisite IRX211 drug-device combination will need to be considered once IRX has obtained HREC approval and further capital has been raised to fund these activities.

IP

An Australian provisional patent application for the Treatment of BTcP was filed at the Australian Patent Office on 21 December 2023 as application number 2023904186.

The Company also has an innovation patent approved and, in consultation with its patent attorneys, has drafted a provisional patent application, which is ready to be lodged in the lead up to the IRX616a Phase 2 clinical trial commencement.

Pain indication

IRX211 clinical trial programme targeting pain

Pivot to BTcP

IRX conducted a pre-IND meeting with the FDA in March 2023, which provided valuable feedback on IRX's roadmap to an NDA for IRX211 as a treatment for CRPS. Whilst supportive overall, some of the feedback received encouraged the Company to reconsider pain indications for which the path to registration required less exploratory work and for which the IRX211 formulation was a closer fit, based on the recent Phase 1 pharmacokinetic ('**PK'**) results.

Following a detailed and careful evaluation process, the Company has decided to promote BTcP as the primary indication of focus for the proposed Phase 2 trial of IRX211. The established path to registration for BTcP offers a significant commercial opportunity for IRX211 and is also expected to substantially reduce the overall amount of exploratory work required and better mitigate regulatory uncertainty (compared to CRPS).

The Company aims to provide therapeutic solutions to market in a cost-effective and time-efficient manner. In contrast to CRPS, the current drugs approved for BTcP are mainly fentanyl-based (opioids). This means that the known registration strategy employed for these products presents a clearer pathway for IRX211 towards a New Drug Approval ('**NDA**').

Key points supporting the pivot are:

1. **Established indication:** BTcP is an established indication compared to the new and exploratory nature of breakthrough pain in CRPS, which requires additional discovery work and increased expenditure.

2. **FDA Vouchers:** IRX may be eligible for three FDA vouchers for BTcP, including Fasttrack, Breakthrough and Accelerated vouchers, providing various advantages such as accelerated approval and market access.

3. **Multiple approvals:** BTcP has multiple existing approvals allowing for a clearer trial design, making the path to approval more apparent.

4. **Single pivotal phase 3 trial:** Given BTcP is an established indication with approved treatments, IRX211 may be able to seek FDA approval for a single pivotal Phase 3 trial (as opposed to the standard pathway which often requires multiple phase 3 trials), potentially resulting in time and cost savings.

5. **Larger patient population for BTcP:** BTcP has a significantly larger estimated patient population compared to CRPS, potentially making recruitment for clinical trials faster and more cost-effective. The increased patient population may make it easier to conduct large-scale clinical trials and gather sufficient evidence to support the drug's efficacy and safety.

6. **Commercial opportunity for BTcP drug:** The commercial opportunity for an approved BTcP drug is substantial. IRX has completed an assessment of this opportunity and the IRX Board is satisfied that

the potential value creation opportunity justifies the adoption of BTcP as the target pain indication for the proposed IRX211 Phase 2 clinical trial programme.

Notwithstanding the above, CRPS remains a viable supplementary pain indication for IRX211 and it is the Company's intention that opportunities for the application of IRX211 for CRPS will be explored further once the BTcP indication pathway is more thoroughly investigated and developed.

What is Breakthrough Cancer Pain ?

According to the 11th revision of the International Classification of Diseases, chronic cancer pain is defined as pain caused by primary cancer itself, metastases or its treatment. BTcP is described as a temporary intensification of such pain that arises either spontaneously or in connection with a particular predictable or unpredictable trigger, even when the background pain is relatively stable and well-controlled.

While the current (mainly opioid-based) therapeutic options play a crucial role in managing pain, their prescription and use requires careful monitoring and adherence to established guidelines to mitigate the significant risks of tolerance, dependence, and opioid-related adverse events. As a result, there is a significant unmet need in the BTcP space for a non-opioid-based rapid-onset analgesic.

It is estimated that approximately half of the adult cancer population experiences BTcP at some point. This can vary based on disease progression, ranging from 39.9% in outpatient clinics to 80.5% in palliative care units[1].

There are an estimated 18.1m cancer survivors living in the US alone[2], with approximately one to two-thirds of patients with advanced cancer and chronic pain experiencing BTcP[3].

IRX211 is aiming to capture a significant share of this market due to its non-opioid nature and rapid onset of action.

Clinical Trials

The Phase 1 trial has been completed for IRX211 with some very promising efficiency insights. There were no serious adverse events and the Board of Directors is delighted with the safety profile as the Company prepares 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 Company anticipates being ready to submit to HREC in Q1 2024.

While the pivot to BTcP (as outlined above) provides the potential for overall significant time and cost savings across the entirety of the clinical development timeline for IRX211 (versus CRPS), the change of focus to BTcP as the primary indication for the Phase 2 trials is initially expected to result in a change in scope for the proposed IRX211 phase 2 trial. This change in scope is currently being evaluated by IRX management, but is

[1] Deandrea S, Corli O, Consonni D, Villani W, Greco MT, Apolone G. Prevalence of breakthrough cancer pain: a systematic review and a pooled analysis of published literature. J Pain Symptom Manage [Internet]. 2014 [cited 2023 Apr 11];47(1):57–76. Available from: https://pubmed.ncbi.nlm.nih.gov/23796584/

[2] https://cancercontrol.cancer.gov/ocs/statistics

3 Davis MP. Breakthrough Pain in Cancer Patients – Characteristics, Impact, and Assessment. US Oncology Hemat 7(1):12, 2011.

expected to require an increase in the number of trial participants versus what was planned for a CRPS focused Phase 2 trial. Accordingly, it is expected that the cost of this trial and its duration will likely exceed what was previously expected. A further up-date will be provided once this evaluation process has been completed.

Mental health indication

IRX616a clinical trial program update targeting anxiety

Clinical Trial

The IB and clinical trial protocol have been finalised. A submission has been made to Bellberry as a nominated HREC. The Company received some valuable insights from the initial HREC feedback on its submission. The Company continues to work closely with Ingenu and the clinical trial site in preparing the necessary information for a resubmission, which is expected to occur in the coming months.

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 IND submission for IRX616a, which it is anticipated will be lodged in Q1 2024.

Payments to Directors & Related Parties

Cash payments to Directors during the December 2023 quarter totaled $23k (including GST) with a further $58k (including GST) paid as salaries to key management personnel.

Use of funds

The Company received $546k through entering into a financing facility with Radium Capital which allowed early access to a part of the R&D tax incentive claim for the 2023 year. There was also an ATO net refund received of $10k related to GST.

During the quarter, funds spent on operating activities comprised:

- $96k in general corporate costs including insurance ($42k); CEO ($27k); CFO ($13k); company secretary ($12k); and other costs ($2k);
- $64k in salaries paid to employees;
- $34k in clinical development costs (including medical writing, regulatory engagement and trial drug manufacturing);
- $34k in auditor fees ($17k); share registry/ASX/ASIC costs ($3k) and investor relations costs ($14k);
- $23k in director fees; and
- $1k in interest charges.

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 to treat Panic Disorder and Breakthrough Cancer Pain using rapid and cost effective regulatory pathways, such as 505(b)(2). A 505(b)(2) application is a NDA that contains full reports of investigations of safety and effectiveness where at least some of the information required for approval comes from studies available in the public domain.

There is a significant economic opportunity for IRX and the Company's shareholders as these carefully selected medical indications under investigation currently have extremely limited treatment options, whilst also offering a low side effect profile.

IRX holds an innovation patent and provisional patents for the nominated indications and the Company plans to continue to strengthen this position.