



ASX Announcement

QUARTERLY ACTIVITIES, CASHFLOW REPORT and OPERATIONS UPDATE

Quarter ended 31 December 2021

InhaleRx Ltd (ASX:IRX) ("InhaleRx" or the "Company") is pleased to provide its quarterly activities, cash flow report and an update of operations.

Operational highlights are as follows:

- Cash reserves at 31st December 2021: \$2,806k
- Net cash used in the quarter for operating activities: (\$283k)
- Appointment of Executive Director
- Successful launch of new Medihale cannabinoid formulations
- White label opportunities for Medihale.

Net cash outflow from operating activities during the quarter was \$283k, with the company continuing to streamline its operations and adopt a disciplined approach to the incurrence of operational expenditure.

Appointment of Executive Director

On 29th December 2021, Mr. Darryl Davies was appointed an Executive Director and assumed responsibility for leading IRX's operations. This followed the resignation of the Company's Chief Executive Officer, Mr. Matthew Golden. Mr. Golden left the Company on that date.

Clinical development pathway up-date

Complex Regional Pain Syndrome (CRPS)



Prevalence:	219,317 ¹ cases in the United States, the total (2017) - <i>Confirmed Orphan Status</i>
TAM:	USA alone is approx. USD \$7.08b² (<i>Calculated by the prevalence x the average rebate under ODD</i>) (2)
Existing Drugs:	No drugs have been specifically approved for CRPS. Patients resort to combination of opioids/lyrica and atypical antidepressants. The sudden onset of pain and time to analgesic effect from current treatments is mismatched.
Likely Pathway:	FDA 505(b)(2), Orphan Drug Designation (ODD)

(1) <https://www.delveinsight.com/report-store/complex-regional-pain-syndrome>.

(2) In 2019, the average annual cost of an orphan treatment per treated patient was \$32,000 (USD),
<https://rarediseases.org/wp-content/uploads/2021/03/orphan-drugs-in-the-united-states-NRD-2020.pdf>



Panic Disorder (PD)

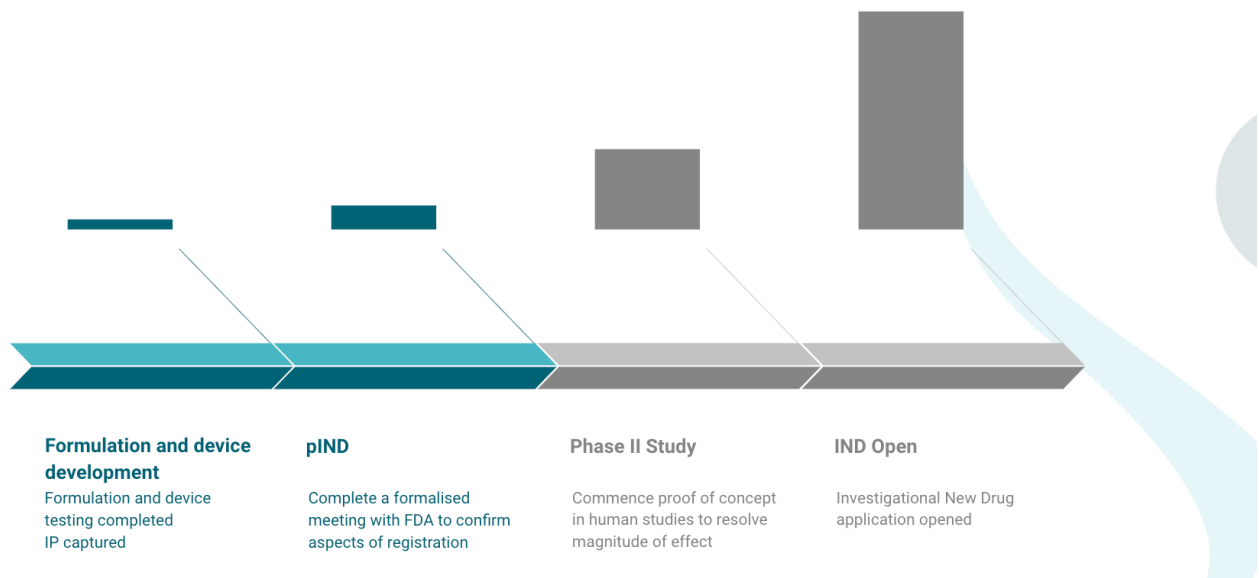
- Prevalence:** 6.97m Americans suffering with Panic Disorder, which is an estimated 2.7% of the U.S. adult population³
- TAM:** USA alone is approx. **USD \$45.15b**⁴ for Panic Disorder (*prevalence x average annulaised medical costs*)
- Existing Drugs:** Antidepressants (SSRI), benzodiazepines, gabapentin, and mirtazapine help to frequency of of attacks.
The sudden onset of panic attacks can currently not be managed satisfactorily.
- Likely Pathway:** FDA 505(b)(2)

(3) Population of the US is 331.4m, of which, 258.3 million were adults. [Facts & Statistics | Anxiety and Depression Association of America. ADAA](#)

(4) Average annual Medical cost of Anxiety Disorder is USD \$6,475 <https://pubmed.ncbi.nlm.nih.gov/16075454/>

Detailed project planning has been completed for the clinical development of inhaled cannabinoid formulations for the treatment of Complex Regional Pain Syndrome (**CRPS**) and Panic Disorder (**PD**).

The overarching goal is to have the formulations approved as a treatment for these conditions by the FDA (USA).



IRX has identified the most suitable inhaled system delivery device (pMDI) for each application and has engaged Camargo Pharmaceutical Services to complete an initial feasibility assessment to confirm suitability for use in IRX's Pre-IND application to the FDA for CRPS.

An Orphan Drug Designation (ODD) has been filed with the FDA for CRPS.

The tender process is underway for selection of a clinical research organisation (CRO) to facilitate the completion of clinical trial studies. IRX is currently shortlisting formulations specialists for CRPS and PD to assist with some of the final stage formulation work required. The Company has also commenced a process of assessing contract manufacturing partners with a view to securing an appropriate supply of the cannabinoid formulations for use in the clinical trials.

The company has engaged two independent contractors, one for medical writing, the other for biostatistical and pharmacokinetic services.

To assist in securing the necessary supply of cannabinoids for use in the clinical trial process, IRX has commenced the process of applying for the necessary wholesale and import/export licenses to allow it to commence sourcing and supplying medicinal cannabinoid medications.

Launch of new Medihale cannabinoid formulations

In early December, InhaleRx in conjunction with its commercial partner, EC Pharma Pty Ltd (“EC Pharma”), successfully launched a new range of cannabinoid formulations, including 1:1 CBD/THC and THC only fills. The early market response to these new formulation lines has been very promising.

Once IRX is in receipt of the necessary wholesale licences (discussed above), it will also be in a position to commence directly marketing its own range of Medihale pod formulations.

White label opportunities for Medihale

The launch of the new formulations, together with the engagement of dedicated business development resourcing has led to a substantial increase in white label opportunities and IRX has recently commenced discussions with a number of parties for this purpose.

During the quarter, the Company signed a commercial supply agreement with Cannim Pty Ltd (Cannim) which will allow Cannim to utilise Medihale® pods and the Medihale® Inhalation device to deliver its own cannabinoid formulations to its patients. The agreement is over the next 2 years with a further 2 year extension available.

There is currently interest from a further four licenced producers looking at leveraging the Medihale device for both cannabinoid and nicotine prescriptions.

Payments to Directors & Related Parties

Cash payments to Non-executive Directors during the quarter totaled \$50k.

Use of funds

During the quarter, funds spent on operating activities comprised:

- \$51k for the purchase of pod inventory;
- \$55k in CEO wages (including the pay-out of accrued entitlements at termination);
- \$8k for PR and marketing materials;
- \$27k for the winding-up of IRX's German subsidiaries; and
- \$142k in general corporate costs including audit fees (\$20k) and legal fees (\$25k).

The Company will provide further updates in due course.

Authorised by the Board of Directors.

For further information:

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- (4) Average annual medical cost of anxiety disorder is USD \$6,475 <https://pubmed.ncbi.nlm.nih.gov/16075454/>