ABN: 89 609 406 911



8 February 2022

# Creso Pharma's wholly-owned psychedelics subsidiary, Halucenex Life Sciences Inc. recognised as licenced psilocybin supplier under Health Canada's Special Access Program (SAP)

# **Highlights:**

- Halucenex now able to provide patients with previously restricted psychedelic substances, under certain circumstances, following Health Canada guidelines
- Regulatory changes to Health Canada's SAP announced on 5 January 2022 reverse a 2013 decision to prohibit the use of psychedelic substances
- Medical professionals can now request access to previously restricted substances, including psilocybin, for emergency and life-threatening treatment from approved suppliers by Health Canada
- Halucenex is one of the several suppliers that doctors and patients who obtain permission will be directed to for the supply of psychedelic substances
- Halucenex leveraging existing networks to establish supply agreements and further advance education initiatives
- Post-Traumatic Stress Disorder (PTSD) therapeutics sector expected to grow to US\$10.5Bn in value by 2025 providing Creso Pharma with a major market opportunity<sup>i</sup>

Creso Pharma Limited (ASX:CPH, OTC:COPHF, FRA:1X8) ('Creso Pharma' or 'the Company') is pleased to advise that its wholly-owned, Canadian based psychedelics subsidiary, Halucenex Life Sciences Inc. ("Halucenex") has been included on a list of companies that can provide psychedelic compounds to researchers and patients under the SAP. The SAP is a federal program that allows healthcare professionals to apply for access to non-marketed medications that have not yet been approved for sale when such medications show clinical evidence of safety and efficacy and are intended to treat patients with severe or life-threatening illness<sup>ii</sup>.

This update follows Halucenex's invitation to become a supplier to Health Canada's SAP after favourable regulatory changes allowed a previously restricted range of psychedelic substances, including psilocybin to be provided to patients under certain emergency circumstances (refer ASX announcement: 11 January 2021).

As previously advised, the changes to the SAP were announced on 5 January 2022 in the Government of Canada's official newspaper, the Canada Gazette. The announcement reversed a 2013 decision that prohibited a range of restricted drugs, including psilocybin in the treatments for mental health and other health conditions.

The new regulations allow medical practitioners, on behalf of patients with serious to life-threatening conditions, to be able to request restricted drugs through the SAP. Halucenex will now be included on a list of several suppliers that will be provided to doctors requesting access to psilocybin for their patients.

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**Halucenex President, CEO and Founder, Mr Bill Fleming said:** "We commend Health Canada's continued progress towards providing treatment options to those needing support to combat serious or life-threatening conditions.

Becoming an approved supplier of psychedelic compounds for the Special Access Program provides Halucenex with a new potential revenue stream and cements our place as one of Canada's leading drug development and supply company.

"It's encouraging to see policy makers begin to recognise the potential for psychedelic medicines for both its medicinal and research capabilities. As the public demand for psychedelic medicines increases, we hope to continue to witness a change in the regulatory landscapes to allow us to fully utilise the application of these innovative medicines. We are now focused on working with our network of partners to begin the supply of our Good Manufacturing Practice (GMP) quality grade synthetic psilocybin to doctors and patients under the SAP."

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# **Authority and Contact Details**

This announcement has been authorised for release by the Board of Directors of Creso Pharma Limited.

For further information, please contact:

# **Investor Enquiries**

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## **About Creso Pharma**

Creso Pharma Limited (ASX:CPH) brings the best of cannabis to better the lives of people and animals. It brings pharmaceutical expertise and methodological rigor to the cannabis world and strives for the highest quality in its products. It develops cannabis and hemp derived therapeutic, nutraceutical, and lifestyle products with wide patient and consumer reach for human and animal health.

Creso Pharma uses GMP (Good Manufacturing Practice) development and manufacturing standards for its products as a reference of quality excellence with initial product registrations in Switzerland. It has worldwide rights for a number of unique and proprietary innovative delivery technologies which enhance the bioavailability and absorption of cannabinoids. To learn more please visit: <a href="https://www.cresopharma.com">www.cresopharma.com</a>

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## **Forward Looking statements**

This announcement contains forward-looking statements with respect to Creso and its respective operations, strategy, investments, financial performance, and condition. These statements generally can be identified by use of forward-looking words such as "may", "will", "expect", "estimate", "anticipate", "intends", "believe" or "continue" or the negative thereof or similar variations. The actual results and performance of Creso could differ materially from those expressed or implied by such statements. Such statements are qualified in their entirety by the inherent risks and uncertainties surrounding future expectations. Some important factors that could cause actual results to differ materially from expectations include, among other things, general economic and market factors, competition, and government regulation.

The cautionary statements qualify all forward-looking statements attributable to Creso and persons acting on its behalf. Unless otherwise stated, all forward-looking statements speak only as of the date of this announcement and Creso has no obligation to up-date such statements, except to the extent required by applicable laws.

i Credence Research Post-Traumatic Stress Disorder Therapeutics Market - Growth, Future Prospects and Competitive Analysis, 2018-2026

 $ii\ https://www.canada.ca/en/health-canada/services/drugs-health-products/special-access.html\\$