ABN: 89 609 406 911



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# Halucenex Life Sciences Inc. continues to make strong progress ahead of Phase II clinical trials

# **Highlights:**

- USP 62 test work underway successful completion of protocols would deem Halucenex's GMP grade psilocybin safe for human consumption
- Testing underway with leading R&D partner Nucro-Technics with final results expected in coming weeks
- Data to build on growing body of evidence of the use of psilocybin and further Halucenex's ongoing R&D efforts
- Discussions with Health Canada regarding receipt of Controlled Drugs and Dealer's License are well progressed expected to be granted imminently
- Dealer's License will allow Creso to progress phase II clinical trial initiatives to test efficacy of psilocybin on treatment resistant PTSD
- Large market opportunity PTSD therapeutics market expected to be valued at US\$10.5Bn by 2025<sup>i</sup>

**Creso Pharma Limited (ASX:CPH, FRA:1X8) ('Creso Pharma' or 'the Company')** is pleased to provide the following update on recent operational progress through wholly-owned, Canadian based psychedelics company, Halucenex Life Sciences ("Halucenex").

As previously advised (refer ASX announcement: 15 July 2021), Halucenex has completed all requirements to satisfy USP 61 conditions, which provide significant validation for the use of its GMP grade psilocybin.

Halucenex has also commenced USP 62 protocols, alongside leading R&D partner Nucro-Technics (refer ASX announcement: 6 May 2021). The USP 62 test evaluates a product for the presence or absence of potential pathogens. USP 62 tests are necessary for cosmetic and personal products to determine that any microorganisms that may be present in a product are not specific pathogenic microorganisms of particular concern if found in a consumer product. Once this test work is complete and if successful, it will deem the Company's products safe for human consumption.

Test work is well progressed and once complete, the data generated will allow Halucenex to further progress its Clinical Trial Authorisation (CTA) with Health Canada. The Company remains in advanced discussions with the regulatory body regarding the status of its Controlled Drugs and Substances Dealer's license (Dealer's License). The Company believes receipt of the Company's Dealer's License is imminent, which will allow further steps to be taken towards the commencement of a phase II clinical trial into efficacy of psilocybin when used for the treatment of Treatment Resistant Post Traumatic Stress Disorder (PTSD).

The PTSD therapeutics market represents a large opportunity for Halucenex and Creso Pharma and is estimated to be worth upwards of US\$10.5Bn by 2025. Pending success in clinical trial initiatives and through additional, planned R&D, Creso Pharma will be well placed to capitalise and grow its market share across the sector.

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# **Commentary:**

**Halucenex Founder & CEO Bill Fleming said**: "There is a significant backlog on current test work and Halucenex has managed to traverse this and achieve very pleasing results around its USP 61 requirements, with initial data indicating a positive outcome for our USP 62 testing.

"The work that has gone into these two testing phases should not be underestimated. Both datasets will provide significant validation of our psilocybin and also indicate that it is safe for human consumption, prior to the commencement of our planned phase II clinical trial.

"We look forward to the receipt of these results in the coming weeks, as well as the outcome and award of our Dealer's License from Health Canada. Discussions with the regulatory body have progressed well and all questions to date have been satisfied."

**Non-executive Chairman Adam Blumenthal said:** "Recent work undertaken by Halucenex has well positioned the Company within the industry. Given the bottleneck of supply around psilocybin and our supply, we are positioned to capitalise as a first mover in the PTSD therapeutics sector.

"We anticipate the receipt of the Dealer's License from Health Canada shortly. This is expected to unlock significant value for our shareholders and allow the Company to further progress its growth strategy.

"As the Company embarks on its proposed merger with Red Light Holland, additional synergies and benefits continue to materialise. Following completion of the merger, the combined company's North American presence will provide a favourable operating jurisdiction to pursue joint venture and licencing agreements with large pharmaceutical companies and other potential industry partners.

"We look forward to updating shareholders on results from the USP 62 results and other regulatory developments over the coming weeks."

-Ends-

### **Authority and Contact Details**

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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

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highest quality in its products. It develops cannabis and hemp derived therapeutic, nutraceutical, and life style 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: www.cresopharma.com

#### About Halucenex Life Science:

Halucenex is a life sciences development company with a focus on researching novel psychedelic compounds, developing and licensing psychedelic compounds for the pharmaceutical and nutraceutical markets, and conducting clinical trials on the medical benefits of psychedelic medicine. Halucenex operates a 6000 sq. ft. medical facility in Windsor, Nova Scotia with 6 treatment rooms and a secure laboratory dedicated to performing psychedelic-assisted psychotherapy and clinical research. Halucenex intends to maintain control over all aspects of the product development process – mycological research, extraction technology, and synthetic formulation as well as drug delivery technologies, psychedelic-assisted psychotherapy and regulatory affairs. www.halucenex.com

# **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.

<sup>&</sup>lt;sup>1</sup> Credence Research Post-Traumatic Stress Disorder Therapeutics Market - Growth, Future Prospects and Competitive Analysis, 2018-2026