



28 February 2022

## **Creso Pharma's wholly-owned psychedelics subsidiary, Halucenex Life Sciences Inc., secures Clinical Trial Authorisation for its phase II clinical trial with Health Canada**

### **Highlights:**

- **Clinical Trial Authorisation ("CTA") granted by Health Canada for Halucenex's planned phase II clinical trial – highlights a major milestone for the Company**
- **Phase II clinical trial planned to test efficacy of psilocybin on treatment resistant Post Traumatic Stress Disorder ("PTSD")**
- **Granting of CTA positions Halucenex as one of the few companies in Canada with clearance to commence a clinical trial utilising psychedelic substances**
- **Patient recruitment process to formally commence – 18 to 20 individuals (over 19 years old) that suffer from treatment resistant PTSD will be enrolled in the trial**
- **Halucenex to leverage existing relationships with veterans affairs organisations to expedite recruitment process**
- **Work with Acadia University towards clinical trial design and ethics approval well progressed**
- **Halucenex anticipates commencement of planned clinical trial during Q2 CY2022**
- **Trial has the potential to unlock major market opportunity for Creso Pharma and access to the PTSD therapeutics sector which is expected to grow to US\$10.5Bn in value by 2025<sup>i</sup>**
- **Success in the clinical trial would allow the Company to progress several near-term opportunities including potential joint venture, licensing, product development and ongoing R&D initiatives**

**Creso Pharma Limited (ASX:CPH, OTC:COPHF, FRA:1X8) ('Creso Pharma' or 'the Company')** is pleased to advise that wholly-owned, Canadian based psychedelics company, Halucenex Life Sciences Inc. ("Halucenex") has secured Clinical Trial Authorisation with Health Canada. This highlights a major milestone for the Company and will allow Halucenex to progress the final steps towards the commencement of its planned phase II clinical trial to test the efficacy of psilocybin on treatment resistant Post Traumatic Stress Disorder.

Clinical Trial Authorisation follows an initial submission from Halucenex to Health Canada (refer ASX announcement: 25 January 2022), which detailed the proposed trials objectives, design protocols and supporting data. This submission was subject to a 30-day review process by the regulator, prior to approval being granted.

Halucenex will immediately progress its patient recruitment objectives. The Company will leverage its established relationships with veterans affairs groups across Canada to expedite this process, while continuing additional work with Acadia University towards clinical trial design and ethics approval. The Company anticipates that the planned clinical trial will commence during Q2 CY2022.



The proposed phase II clinical trial is designed to be a single-arm, open-label trial that will ultimately determine the feasibility of future trials of psilocybin in this indication. It is planned that 18 to 20 individuals (over 19 years old) that suffer from treatment resistant PTSD will be enrolled in the trial.

Success in the clinical trial would allow Halucenex to progress a number of potential opportunities in the PTSD therapeutics sector. This is a large addressable market for the Company and is expected to reach a value of US\$10.5Bn by 2025<sup>1</sup>. Subsequent to the completion of the clinical trial and subject to success in the trial, Halucenex will pursue potential joint venture, licensing, product development and ongoing R&D initiatives.

**Commentary:**

**Halucenex President, CEO and Founder Mr Bill Fleming said:** *“Securing Clinical Trial Authorisation solidifies over 16 months of hard work and dedication from our team and positions Halucenex as one of very few Canadian companies with approval to commence a clinical trial utilising psychedelic substances on mental health conditions.*

*“We will immediately commence the formal patient recruitment process. Given our longstanding relationships with a number of veterans affairs groups and the prevalence of treatment resistant PTSD across North America, we anticipate that this will be a seamless process. We look forward to providing additional updates to shareholders as we continue our rapid progress.”*

**-Ends-**

**Authority and Contact Details**

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

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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 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](http://www.cresopharma.com)

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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.

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<sup>1</sup> Credence Research PTSD Therapeutics Market - Growth, Future Prospects and Competitive Analysis, 2018-2026