



25 January 2022

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

Highlights:

- **Submission of the Clinical Trial Authorisation ("CTA") is an important step ahead of Halucenex planned phase II clinical trial**
- **CTA is subject to 30-day review by Health Canada and approval from Health Canada, if obtained, will allow Halucenex to commence its clinical trial during Q2 CY2022**
- **Phase II clinical trial planned to test efficacy of psilocybin on treatment resistant Post Traumatic Stress Disorder ("PTSD")**
- **Clinical trial is expected to add to the growing body of evidence for the use of psilocybin assisted psychotherapy which may derisk uptake and rollout**
- **Following successful completion of the trial, multiple opportunities for Halucenex may exist in the form of licencing and joint ventures**
- **Trial design and ethics approvals are advanced – demand from potential patients also being witnessed**
- **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 2025ⁱ**

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 lodged its Clinical Trial Authorisation ("CTA") with Health Canada. This is an important step ahead of Halucenex's planned phase II clinical trial.

The CTA will be subject to a 30-day review and approval by Health Canada. The lodgement follows recent amendments to the Company's Controlled Drugs and Substances Dealer's Licence from Health Canada ("Dealer's Licence") (refer ASX announcement: 2 December 2021).

The submission of the CTA is an important step in allowing Halucenex to prepare its planned phase II clinical trial to test the efficacy of psilocybin on treatment resistant Post Traumatic Stress Disorder (PTSD). 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.

Additional work towards trial design and ethics approval has been advanced in collaboration with Acadia University (refer ASX announcement: 20 September 2021). Halucenex also intends to embark on patient recruitment initiatives following approval from Health Canada, which should allow the Company to commence its planned clinical trial during Q2 CY2022. Strong demand from potential patients is already being witnessed.



The Company expects that success in the clinical trial will leave Halucenex well placed to progress a number of potential opportunities in the PTSD therapeutics sector, which is expected to reach a market value of US\$10.5Bn by 2025¹. Upon completion of the clinical 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: *“Lodging our CTA with Health Canada is the culmination of considerable hard work from the Company. It includes a significant amount of data that has been generated from initiatives over the last 12 months and we are confident that the regulator will find our application more than sufficient. This marks the first milestone of many in the commencement of our planned clinical trial, which has the potential to significantly shift the way people utilise psychedelics as an alternative treatment route.*

“If approval from Health Canada is obtained, Halucenex will hold another significant competitive advantage and be in a position to commence its clinical trial during Q2 CY2022. We are witnessing demand from potential trial participants and making strong progress with our key partners. We look forward to providing additional updates in the coming weeks.”

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Authority and Contact Details

This announcement has been authorised for release by the CEO and Managing Director 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 Practices) 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

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Forward Looking statements

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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.

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