



7 December 2022

## **Wholly-owned psychedelics subsidiary, Halucenex Life Sciences Inc. administers first doses of 100%-owned and formulated synthetic psilocybin product in phase II clinical trial**

### **Highlights:**

- **Initial dosage of 100%-owned and formulated Lucenex branded 10mg and 25mg synthetic psilocybin product administered to first clinical trial participant with no observed adverse effects**
- **Clinical trial will test the efficacy of psilocybin on treatment resistant Post Traumatic Stress Disorder (PTSD)**
- **Halucenex has dosed its first patient with doses of both 10mg and 25mg of synthetic psilocybin (in separate sessions) and under the current trial design will average dosages of two patients per week going forward**
- **Each participant will receive one 10mg microdose and then a 25mg macrodose**
- **20 participants successfully recruited for trial – all suffer from PTSD and other mental health disorders including (but not limited to) anxiety, depression, ADHD and OCD**
- **Trial expected to complete during Q2 2023**
- **Halucenex to pursue additional clinical trial protocol amendment with Health Canada to investigate sleep disruption, which is one of the most impactful PTSD symptoms**
- **Clinical trial amendment will also seek to alter the clinical trial score requirement for the severe PTSD indication**
- **The global sleep aid market size is a large addressable market, predicted to be worth US\$97.3Bn by 2027<sup>i</sup>**
- **A successful trial outcome has the potential to unlock major market opportunity for Creso Pharma and unlock access to the PTSD therapeutics sector which is expected to grow to US\$10.5Bn in value by 2025<sup>ii</sup>**

**Creso Pharma Limited (ASX:CPH, FRA:1X8) ('Creso Pharma' or 'the Company')** is pleased to report that wholly-owned, Canadian based psychedelics company, Halucenex Life Sciences Inc. ("Halucenex") has successfully administered first doses of its Lucenex branded 10mg and 25mg synthetic psilocybin formulation to a patient participating in the Company's phase II clinical trial (in separate sessions), marking the commencement of the initiative. The dosage has not shown any observed adverse effects.

Halucenex's clinical trial is a single-arm, open-lab trial that will test the efficacy of psilocybin on treatment resistant Post Traumatic Stress Disorder (PTSD) and ultimately determine the feasibility of future trials of psilocybin in this indication (refer ASX announcement: 28 February 2022).

The Company has successfully recruited 20 participants for the trial (refer ASX release 6 October 2022). All of which suffer from PTSD, as well as other mental illnesses including (but not limited to) anxiety, suicidal thoughts, ADHD, OCD, depression and anger.



Following ongoing work alongside participants, Halucenex has also made the strategic decision to seek an amendment to its clinical trial with Health Canada to investigate sleep disruption, which is seen as one of the most impactful PTSD symptoms.

Further, the Company will seek to alter the clinical trial score requirement into the severe PTSD indication. This process is underway and the Company will continue to progress the trial in the interim.

Following the administration of its 100%-owned and formulated synthetic psilocybin aqueous solution, Lucenex to the first patient, Halucenex will continue administering its synthetic psilocybin to an average of two patients per week (pending the aforementioned amendment), allowing for completion in Q2 CY2023.

Upon completion and subject to the success of the trial, Halucenex will undertake an extensive review of data generated and the effect of synthetic psilocybin when used to treat symptoms associated with PTSD. The Company will also simultaneously conduct a review of additional product development opportunities, R&D initiatives and potential licencing agreements.

#### **Commentary:**

**Halucenex CEO and Founder Mr Bill Fleming said:** *“Administering first dosages of our 100%-owned and formulated synthetic psilocybin follows a considerable amount of work undertaken by Halucenex in the recent months and highlights the potential opportunity that the Company has at hand. Having witnessed no adverse effects from the initial dose also provides us with confidence in moving to the next phase.*

*“Having now completed the first patient dose, we look forward to continuing to work with our clinicians over the coming weeks to complete the administration of psilocybin and monitor patients for improvement in symptoms. The Company expects to be in a position to provide additional updates on developments over the course of the trial.”*

**-Ends-**

#### **Authority and Contact Details**

This announcement has been authorised for release by the Disclosure Committee 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>i</sup> <https://www.marketdataforecast.com/market-reports/global-sleep-aids-market>

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