



14 September 2022

## **Wholly-owned psychedelics subsidiary, Halucenex Life Sciences Inc. secures Research Ethics Board approval and commences patient recruitment for phase II clinical trial**

### **Highlights:**

- **Research Ethics Board (“REB”) approval and patient recruitment were the final steps prior to Halucenex being able to commence phase II clinical trial**
- **Planned clinical trial will test the efficacy of psilocybin on treatment resistant Post Traumatic Stress Disorder (PTSD)**
- **Company to utilise its Lucenex branded 10mg and 25mg psilocybin finished product formulation throughout the trial**
- **Approval demonstrates that all documentation, trial processes and protocols are in line with stringent ethical and safety guidelines**
- **Developments follow amendment to Halucenex’s Clinical Trial Authorisation (“CTA”) from Health Canada**
- **Amended CTA provides scope to broaden clinical trial participants and collect more substantial data sets**
- **Patient recruitment now underway – a number of domestic and international requests have been received and the recruitment is expected to be completed shortly**
- **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>**

**Creso Pharma Limited (ASX:CPH, FRA:1X8) (‘Creso Pharma’ or ‘the Company’)** is pleased to advise that wholly-owned, Canadian based psychedelics company, Halucenex Life Sciences Inc. (“Halucenex”) has received Research Ethics Board (“REB”) approval for all documentation and procedures associated with its phase II clinical trial.

Following the receipt of the REB approval, the Company has now completed all required approvals ahead of its clinical trial, which is designed to test the efficacy of psilocybin on treatment resistant Post Traumatic Stress Disorder (PTSD). Halucenex will utilise its 100%-owned and formulated synthetic psilocybin aqueous product Lucenex during the trial in both 10mg and 25mg formats.

The Ethics Board approval follows a recent amendment to its Clinical Trial Authorisation (“CTA”) from Health Canada to allow patient cohorts currently using Selective Serotonin Reuptake Inhibitors (SSRIs) and not require potential participants to cease using prescription medications for a week prior to the trials commencement. This allows Halucenex to capture a broader data set through a wider group of participants and on how psilocybin interacts when used in combination with other medications utilised by PTSD sufferers (Refer to ASX Release: 22 August 2022).

The Company has also commenced the patient recruitment process through online portals. Over recent months, Halucenex has received a number of domestic and international enquiries regarding



participation, and has begun reviewing and short listing these applications. Halucenex expects to complete patient recruitment protocols shortly.

Success in the trial would provide Creso Pharma with access to the major market associated with PTSD therapeutics. The total PTSD therapeutics sector continues to grow rapidly, underpinned by a need for alternatives to existing pharmacological interventions and is expected to grow to US\$10.5Bn in value by 2025<sup>ii</sup>.

#### **Commentary:**

**Halucenex CEO and Founder Mr Bill Fleming said:** *“Being granted Ethics Board approval for the trial is a very important step in our R&D initiatives. Firstly, it highlights that the carefully designed process and protocols are in line with stringent regulations and will protect the dignity, rights, safety and welfare of all trial participants. Secondly, it will allow the Company to commence the planned clinical trial into a condition as harmful as PTSD.*

*“Halucenex’s management and clinical trial staff have mobilised quickly following the REB approval and begun the patient recruitment process. We have received a significant amount of in-bound enquiries, which further highlights the importance of our planned trial. We look forward to providing updates to shareholders, as required.”*

**-Ends-**

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

This announcement has been authorised for release by the Disclosure Committee 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 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**

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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.

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

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