



2 December 2021

## **Creso Pharma's wholly-owned Canadian psychedelics subsidiary, Halucenex Life Sciences Inc. awarded Controlled Drugs and Substances Dealer's Licence Amendment from Health Canada**

### **Highlights:**

- Halucenex's Controlled Drugs and Substances Dealer's Licence from Health Canada ("Dealer's Licence") upgraded to include production and packaging amendments
- Halucenex now possesses the most extensive licence in regards to Controlled Drugs and Substances that can be awarded by Health Canada, which is anticipated to be a major competitive advantage – with all 5 possible licence categories now granted
- Additions to Dealer's Licence allow Halucenex to commence manufacturing of synthetic and botanical psilocybin and other psychedelic compounds
- Growing process and additional synthetic product formulation to commence imminently, alongside equipment commissioning , extraction and formulation protocols
- Manufacturing and sales capacity has the potential to unlock additional revenue streams for Halucenex through the sale of finished psilocybin product to other licence holders
- Initial discussions underway with potential customers across Canada to use Halucenex's products in clinical trial and R&D settings
- Subject to favourable legislation, Halucenex could be one of very few companies that can provide finished psilocybin to patients, doctors and clinics for medical purposes
- Amendments are expected to provide significant competitive advantages and allow the Company to broaden its scope of work
- Additional R&D, clinical trial processes, comparative studies and extraction initiatives to progress potential product development and licencing opportunities
- Additional R&D and genetic studies anticipated to provide strong basis for product formulation and allow Halucenex to pursue licencing and joint venture opportunities
- Studies to add to the growing body of evidence for the use of psilocybin – this is expected to allow for ongoing data collection, strengthened IP and potential government relations initiatives
- Amended Licence provides strong foundation for Halucenex to lodge Clinical Trial Authorisation ("CTA") with Health Canada
- CTA lodgement expected to occur in the coming weeks – providing a strong basis for the Company to progress phase II clinical trial
- Phase II clinical trial to test efficacy of psilocybin on treatment resistant PTSD expected to commence Q2 CY2022



**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 an amendment to its Controlled Drugs and Substances Dealer's Licence from Health Canada ("Dealer's Licence") on 29 November 2021 (refer ASX announcement: 16 August 2021).

The amendments allow the Company to now produce, package and assemble psychedelic substances including psilocybin, ketamine, LSD, salvia divinorum, harmaline, salvininorin A, and MDMA amongst others ("Approved Controlled Substances").

The additions follow the receipt of an initial Dealer's Licence in August 2021, allowing Halucenex to possess, sell, transport, deliver and conduct R&D on the Approved Controlled Substances. The final amendments provide Creso Pharma with the most comprehensive approvals that can be awarded by Health Canada in relation to controlled substances.

Following the receipt of the amendments, Halucenex intends to commence the growing of its own botanical psilocybin and manufacturing of synthetic psilocybin. This will allow for detailed comparative studies, formulation testing, internal clinical trials, additional extraction opportunities and the sale of finished goods and products to other licenced dealers unlocking another potential revenue stream for the Company.

Given the supply bottleneck of psilocybin for research purposes, Halucenex is witnessing a high level of demand for both botanical and synthetic psilocybin and has fielded a number of enquiries from potential customers. Once growing and formulation processes are complete, Halucenex will be well placed to progress the sale of its products to other licenced dealers across Canada. This is expected to unlock an additional revenue stream for the Company.

Further, should the legislation regarding the use of psilocybin and other controlled substances change, Halucenex would be able to provide both synthetic and botanic psilocybin to doctors, clinics and patients for medical purposes.

Halucenex will also be able to conduct more in-depth R&D on both its own botanic and synthetic psilocybin. This will include extraction studies, product formulation and genetic studies, allowing the Company to gain a much better understanding of psilocybin-based Active Pharmaceutical Ingredients and how these can be used across multiple delivery methods.

The Company is confident that further in-house studies will add to the growing body of evidence for the use of psilocybin and may lead to potential shifts towards reimbursement from large regulatory and government bodies. The ongoing R&D will also assist Halucenex to cater specific formulations for potential licencing and joint venture opportunities.

The licence amendment will provide a strong basis for the Company to lodge its Clinical Trial Authorisation with Health Canada to progress its planned phase II clinical trial to test the efficacy of psilocybin on treatment resistant Post Traumatic Stress Disorder (PTSD). The Company continues to work through the application and expects to lodge the application with the regulatory body in the coming weeks.

The amended Dealer's Licence will be valid until 31 August 2022 and thereafter, be subject to Health Canada's standard licence renewal process, which is in line with Health Canada's standard policies. Further details on the scope of the Dealer's Licence are set out in the Company's release dated 16 August 2021.

**Commentary:**

**Halucenex CEO and Founder Mr Bill Fleming, added:** *"To be awarded the final components of our Dealer's Licence from Health Canada is a major achievement for Halucenex. It follows extensive reviews of documentation and site security from the regulator, illustrating the high standard of our operations.*

*"The amendments provide Halucenex with the most comprehensive licence it could possibly obtain at this stage and is anticipated to unlock significant competitive advantages. We will now begin the steps towards synthetic psilocybin manufacture and botanical psilocybin growing immediately. Both of these initiatives have the potential to deliver a number of commercial and R&D benefits and will shape future product development, clinical trials and potential licencing agreements. Further, this will allow the Company to leverage its extraction facilities and begin working towards completing our clinical trial authorisation with Health Canada.*

*"This development has placed us ahead of some of our competition and we look forward to expediting a number of activities to drive growth."*

**-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**

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