



16 August 2021

Wholly-owned psychedelics subsidiary Halucenex Life Sciences Inc. secures monumental Controlled Drugs and Substances Dealer's Licence from Health Canada

Highlights:

- **Controlled Drugs and Substances Dealer's Licence allows Halucenex to possess, sell, transport and conduct R&D on a broad range of psychedelic substances including psilocybin, ketamine, LSD and MDMA amongst others**
- **Halucenex is now one of few companies globally with a Dealer's Licence and the ability to work with psilocybin and other psychedelics with Health Canada approval**
- **Licence significantly increases scope of work in regards to psychedelics and is expected to fast track phase II clinical trial to test psilocybin on treatment-resistant PTSD**
- **Clinical Trial Application (CTA) lodgement to be expedited – success in trial would unlock a number of future revenue-generating opportunities**
- **PTSD therapeutics market expected to reach a US\$10.5Bn valuation by 2025ⁱ**
- **Established operations in Nova Scotia will provide direct access to a large target market population of veterans – located near some of Canada's largest army and naval bases**
- **Halucenex to leverage licence and further establish itself as one of the world's leading psychedelics companies**
- **Additional product development and integration opportunities to commence with Mernova Medicinal Inc. as well as other partners**
- **Further partnership and licensing agreements expected to materialise allowing Halucenex to become a leader in evolutionary treatment routes**
- **Unlocks access to a large and lucrative opportunity – psychedelic drug market expected to grow to US\$6.8Bn by 2027ⁱⁱ**

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") secured a Controlled Drugs and Substances Dealer's Licence ("Dealer's Licence") from Health Canada on 11 August 2021.

This is a major achievement for Halucenex and will allow the Company to progress its planned phase II clinical trial to test the efficacy of psilocybin on treatment-resistant post-traumatic stress disorder (PTSD).

The Dealer's Licence allows Halucenex to possess, sell, provide, transport, deliver and conduct R&D on psychedelic substances including psilocybin, ketamine, LSD, Salvia divinorum, harmaline, salvinorin A, and MDMA amongst others ("**Approved Controlled Substances**"). As previously announced, the Company will also immediately seek an amendment to the Dealer's Licence to allow Halucenex to produce, package, and assemble the Approved Controlled Substances.



The Dealer's Licence is valid until 31 August 2022, and thereafter is subject to Health Canada's standard licence renewal process, which is in line with Health Canada's standard policies. Under the Dealer's Licence, Halucenex may sell or provide the Approved Controlled Substances in the following circumstances:

- In the case of substances covered by the Canadian *Food and Drug Regulations* (including Salvia divinorum and salvinorin A, GHB, harmaline, LSD, DMT and MDMA), sales are restricted to research/clinical institutions (including other licensed dealers), the Minister, medical practitioners (with the proper exemptions) for the purpose of identification or analysis; and
- In the case of narcotics that are covered by the Canadian *Narcotic Control Regulations* (including ketamine and phencyclidine), sales are restricted to other licensed dealers, pharmacists, medical practitioners, hospital employees, section 56 exemption holders, and the Minister.
- In the case of psilocybin, the Dealer's Licence allows Halucenex to sell or provide psilocybin to other licensed dealers and, upon pre-approval by Health Canada, to Part J (of the *Food and Drug Regulations*) authorization holders for the purposes of clinical testing or laboratory research only.

Recent studies from John Hopkins University and other leading researchers have shown the benefits of psychedelic substances in treating a range of mental health issuesⁱⁱⁱ. Halucenex will leverage the Dealer's Licence to further integrate itself as one of the world's leading companies in the emerging psychedelic assisted therapies sector.

Steps towards a planned phase II clinical trial:

The Company will now expedite its clinical trial application (CTA) with Health Canada, which is a key step in the commencement of its phase II clinical trial to test the efficacy of psilocybin on treatment-resistant PTSD. The Company will lodge its CTA with the regulatory body in the coming weeks, which will be subject to a 30-day review with Health Canada.

Prior to the receipt of its Dealer's Licence, Halucenex has made considerable progress towards the trial and secured a number of key partnerships allowing for patient recruitment, post trial care and initial testing of its psilocybin product.

Most recently, all USP 61 test work has been completed with USP 62 protocols underway (refer ASX announcement: 4 August 2021). Once finalised, this will deem the Company's product safe for human consumption.

Upon completion and the prospective success of the phase II clinical trial, Halucenex will be well placed to pursue a number of opportunities in the PTSD therapeutics sector. This is a large addressable market, estimated to be worth up to US\$10.5Bn by 2025ⁱ. The Company will also take advantage of existing relationships with veterans affairs groups in Canada and other government organisations to unlock significant value for shareholders.



Commentary:

Halucenex Founder & CEO Bill Fleming said: *"The receipt of our Dealer's Licence is the result of a stringent due diligence process undertaken by Health Canada, as well as ongoing consultations with the regulatory body which have highlighted the exceptional standards of our operations and R&D protocol.*

"To date, we have been focused on the lead up to this milestone and have done a lot of essential preparatory work in anticipation of receipt of the Dealer's Licence, which will provide us with a significant competitive advantage as we progress our entry into the lucrative psychedelics drug space.

"We are now very well placed to deliver on a number of value accretive initiatives, which have the potential to unlock significant value for shareholders and further cement our standing as a leader in emerging psychedelic inspired therapies."

Incoming Chairman of The HighBrid Lab Bruce Linton said: *"We are very eager to begin working with Halucenex ahead of the creation of The HighBrid Lab and explore opportunities which will increase the uptake and availability of psychedelics as an evolutionary treatment route to existing therapies.*

"As the mental health crisis continues to unfold, the need for effective treatments is becoming much clearer. The potential and requirements for new treatment pathways is also becoming widely recognised by regulatory bodies, governments and large pharmaceutical companies – all of which provide us with a number of avenues as we embark on test work, R&D and commercialisation."

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Authority and Contact Details

This announcement has been authorised for release by the Board 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



About Halucenex Life Science:

Halucenex is a life sciences development company with a focus on researching novel psychedelic compounds, developing and licensing psychedelic compounds for the pharmaceutical and nutraceutical markets, and conducting clinical trials on the medical benefits of psychedelic medicine. Halucenex operates a 6000 sq. ft. medical facility in Windsor, Nova Scotia with 6 treatment rooms and a secure laboratory dedicated to performing psychedelic-assisted psychotherapy and clinical research. Halucenex intends to maintain control over all aspects of the product development process – mycological research, extraction technology, and synthetic formulation as well as drug delivery technologies, psychedelic-assisted psychotherapy and regulatory affairs.

www.halucenex.com

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.

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

ⁱⁱ <https://www.databridgemarketresearch.com/reports/global-psychedelic-drugs-market>

ⁱⁱⁱ <https://www.hopkinsmedicine.org/news/newsroom/news-releases/psychedelic-treatment-with-psilocybin-relieves-major-depression-study-shows>