



11 January 2022

Creso Pharma's wholly-owned psychedelics subsidiary, Halucenex Life Sciences Inc. invited to become Special Access Program drug supplier following favourable legislative changes

Highlights:

- **Recent regulatory changes to Canada's Special Access Program (SAP) to allow a range of previously restricted drugs, including psilocybin to be used in patient treatment**
- **Regulatory shift announced on 5 January 2022 in the Canada Gazette - follows a 2013 decision by Health Canada banning the use of psychedelic substances**
- **Under new framework, medical professionals can now request access to previously restricted drugs such as psilocybin for the purposes of emergency treatment**
- **Halucenex has been invited to become a supplier to SAP – if obtained, approval is expected to unlock a number of near term revenue generating opportunities for Halucenex**
- **Regulatory shift highlights near term opportunity for Halucenex to supply psilocybin to a growing patient population in Canada**
- **Approval process with Health Canada has begun– Halucenex has supplied a range of data to support the safety and efficacy of its GMP grade psilocybin**
- **Halucenex personnel are advancing discussions with medical professionals and clinics, as well as leveraging established relationships in anticipation for potential supply agreements**
- **Access to the PTSD therapeutics sector is a potential major market opportunity for Creso Pharma with the sector 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 subsidiary, Halucenex Life Sciences Inc. ("Halucenex") has been invited to register as a potential supplier to Health Canada's Special Access Program ("SAP"), following recent regulatory changes.

The amendments to the SAP were announced in the Government of Canada's official newspaper, the Canada Gazette on 5 January 2022ⁱⁱ and reverse a 2013 decision that prohibited a range of restricted drugs, including psilocybin to be used as treatments for mental health and other conditions.

Halucenex will progress the approval process following favourable legislative shifts by the governing body, which if obtained and subject to discretion from Health Canada on a case-by-case basis, will allow the sale of some restricted drugs, including psychedelic substances by medical professionals for the purposes of emergency treatmentⁱⁱ.

Under the new regulatory framework, medical practitioners will, on behalf of patients with serious or life-threatening conditions, be able to request restricted drugs through the SAP. If an individual's application has been granted through the SAP, doctors and patients may be directed to Halucenex as a potential supplier of psychedelic drugs (subject to Halucenex's SAP application being successful).



This presents an opportunity for Halucenex, as it will enable the Company to supply psilocybin to healthcare professionals seeking evolutionary treatments for patients through the SAP. Being classed as a potential supplier is expected to unlock a number of near-term revenue generating opportunities through the sale to medical professionals and patients, as well as the ability for Halucenex to established itself as one of Canada's first potential providers through the SAP.

The Company is in well progressed discussions with Health Canada to advance approval. Halucenex has responded to a request for a dataset from the regulator, which provides background to support the safety and efficacy of the Company's GMP grade psilocybin as a treatment, as well as anticipation of dealership readiness to meet SAP demand for quality-controlled drugs containing psilocybin. Discussions are expected to continue over the coming weeks and the Company looks forward to providing additional updates throughout the authorisation process.

Upon potential approval, Halucenex will begin working with its network of medical professionals and clinics to advance educational initiatives and potential supply agreements. The Company has strong links to a range of veterans affairs organisations, which it will leverage to progress potential sales.

Halucenex founder and CEO, Mr Bill Fleming said: *"Psychedelic medicines remain on a strong upward trajectory for both research and compassionate use purposes and this recent shift from Health Canada shows the potential direction towards more liberal policies as public demand increases.*

"Halucenex is well positioned to capitalise as a supplier to the SAP upon regulatory approval. If successful in the application process, Halucenex has a large supply of GMP grade, synthetic psilocybin which can be sold to doctors and patients. Further, we continue to work through growing protocols for botanical psilocybin, which can also be supplied in the future. Post approval, we anticipate a number of revenue generating opportunities to materialise as Halucenex progresses its transition to a leading drug development and supply company."

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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

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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.

ⁱ Credence Research Post-Traumatic Stress Disorder Therapeutics Market - Growth, Future Prospects and Competitive Analysis, 2018-2026

ⁱⁱ <https://www.gazette.gc.ca/rp-pr/p2/2022/2022-01-05/html/sor-dors271-eng.html>