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Halucenex Life Sciences Inc. makes strategic decision to expand phase II clinical trial beyond veterans and first responders

Highlights

- Decision to broaden trial participants and include participants that have not served in the military who suffer from Treatment Resistant PTSD
- Follows a significant number of inbound enquiries received from people living with debilitating mental health conditions seeking alternative treatment routes
- COVID-19 has accelerated the target market for Halucenex during the pandemic 4 out of 10 US adults have reported symptoms of anxiety or depressionⁱ
- Initiative will provide real world examples of how people treated with psychedelic compounds can reintegrate into the workplace and other activities
- Trial expansion will demonstrate how psychedelic treatments can be used while operating daily routines to assist in a more healthy and efficient manner
- Halucenex expects that the additional data will add to the growing body of evidence for psilocybin use and assist with upcoming research, regulatory and licencing agreements
- This additional data will provide a significant competitor advantage and "first mover advantage" to Halucenex, as this data will be extremely rare and valuable
- Large market opportunity PTSD therapeutics market expected to grow to US\$10.5Bn by 2025ⁱⁱ
- Mental illness in Canada is estimated to have an economic burden of C\$51Bn annuallyⁱⁱⁱ
- Controlled Drugs and Dealer's License from Health Canada expected to be granted shortly

Creso Pharma Limited (ASX:CPH, FRA:1X8) ('Creso Pharma' or 'the Company') is pleased to advise that target acquisition company Halucenex Life Sciences ("Halucenex") has made the strategic decision to expand the recruitment of its phase II clinical trial to include participants that have not served in the military or undertaken roles as first responders, who are suffering from Treatment Resistant Post Traumatic Stress Disorder (PTSD).

The decision to expand the trial scope was made following the overwhelming amount of inbound enquiries that the Company has received from individuals that suffer from debilitating mental health conditions and are seeking alternative treatment methods.

Halucenex anticipates that the addition of non-veterans to the clinical trial will allow it to collate an additional data set, providing 'real world' examples of the efficacy of psilocybin when used as an alternative treatment route.

The Company will utilise this data to progress discussions with potential partners including drug developers and large pharmaceutical companies, as well as insurance providers and regulatory bodies to further cement its position as a first mover in the emerging psychedelics medicines space.



Halucenex expects to commence its phase II clinical trial following the receipt of a Controlled Drugs and Substances Dealer's License (Dealer's License) from Health Canada. Upon receipt of the Dealers License, Halucenex intends to apply for Clinical Trial Authorisation and commence the clinical trial. Discussions with Health Canada are well progressed and the Company anticipates that it will secure its Dealer's License shortly.

While the prevalence of PTSD is higher among veterans than the general population, the market for PTSD therapeutics is expected to grow to US\$10.5Bn by 2025ⁱ. Mental illness in Canada more broadly has an economic burden of C\$51Bn per annumⁱⁱ, highlighting the large market opportunity for Halucenex and Creso Pharma.

Commentary:

Halucenex Founder & CEO Bill Fleming said: "The inclusion of non-veterans in our pending clinical trial is a strategic decision that will provide a number of benefits to Halucenex and Creso Pharma. Following various regulatory shifts in the US and the exacerbating effect COVID-19 has had on mental health conditions across the population, it is becoming more and more apparent that psychedelic treatments could become mainstream in the near future, so to include every day people in our R&D will provide us with examples of how psilocybin can be used more broadly to treat mental health issues."

"Further, expanding the trial scope will add to the growing body of evidence for psychedelic based medicines, and assist the Company as it progresses further research and licensing agreements in North America and more broadly."

Non-executive Chairman Adam Blumenthal said: "Halucenex's management continue to make steps towards creating psychedelic compounds and therapeutics that can be used for both veterans and first responders, as well as every day individuals. To broaden the clinical trial participant scope, is a very promising development and will lay a very strong foundation for the Company as it pushes towards becoming a best-in-class provider of cannabis, cannabinoids and psychedelic alternative medicines, to meet the growing need for treatments to improve wellbeing."

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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.

¹ https://www.kff.org/coronavirus-covid-19/issue-brief/the-implications-of-covid-19-for-mental-health-and-substance-use/ ¹¹Credence Research Post-Traumatic Stress Disorder Therapeutics Market - Growth, Future Prospects and Competitive Analysis, 2018-2026 ¹¹Smetanin et al. (2011). The life and economic impact of major mental illnesses in Canada: 2011-2041. Prepared for the Mental Health Commission of Canada. Toronto: RiskAnalytica