



15 March 2021

Agreement to acquire established Canadian psychedelics company Halucenex Life Sciences Inc.

Highlights

- **Halucenex is a Psychedelic-Assisted Psychotherapy (PAP) company**
- **Halucenex focuses on the commercialisation and R&D of novel psychedelic molecules for the treatment of Post Traumatic Stress Disorder (PTSD), Depression and other mental illnesses**
- **Agreement provides Creso Pharma with entry into the emerging global market for psychedelics medicines – estimated to be worth up to US\$100Bnⁱ**
- **Acquisition marks the first 100%-owned psychedelic medicines company on the ASX**
- **PTSD therapeutics market is expected to grow to US\$10.5Bn by 2025ⁱⁱ and mental illness in Canada has an economic burden of C\$51Bn per annum^{iii,iv}**
- **Halucenex operates a 6,000 sq. ft. medical clinic dedicated to the treatment of mental illness located adjacent to an emergency hospital**
- **On receipt of its Dealer's License, Halucenex will be permitted to possess and conduct R&D of psychedelic molecules including psilocybin**
- **Focused on synthetic psilocybin, the active ingredient in magic mushrooms which has been shown to have considerable evidence-based mental health benefits**
- **Path to early revenues through strategic affiliation with Veterans Affairs Canada and Veteran support groups via veteran and advisor David Fraser, retired NATO general**
- **Multiple near-term value catalysts – licencing deals and clinical trial milestones pending**
- **Delivers a new highly lucrative industry vertical and additional future revenue stream**
- **Highly experienced team with a track record of commercialising successful businesses**
- **Halucenex will benefit from significant synergies including Creso Pharma's experienced pharmaceutical product development team, industry leading advisers, a comprehensive global distribution network and a top-tier premium cannabis cultivation facility**

Creso Pharma Limited (ASX:CPH, FRA:1X8) ('Creso Pharma' or 'the Company') is pleased to advise that it has signed an agreement to acquire Halucenex Life Sciences Inc. ("Halucenex"), an established psychedelics company focused on developing treatments for Treatment Resistant Depression in individuals suffering from PTSD, and other mental health illnesses (**Acquisition**).

Based in Nova Scotia, Canada, Halucenex is a life sciences development company focused on researching, developing and licencing novel psychedelic molecules for the global pharmaceutical and nutraceutical markets. Halucenex is currently focused on progressing clinical trials to research the efficacy of psilocybin to treat and alleviate Treatment Resistant Depression in individuals suffering from PTSD and other mental illnesses.



The proposed acquisition provides Creso Pharma with a first mover advantage into the psychedelic medicines sector and marks the first 100%-owned psychedelic medicines company listed on the ASX.

The acquisition of Halucenex is transformational for Creso Pharma. The Company will emerge as a best-in-class provider of cannabis, cannabinoids and psychedelics alternative medicines to meet the large unmet need for treatments to improve mental health and well being.

Halucenex – an established Canadian psychedelics company:

Halucenex is focused on delivering and developing evidence-based products for the treatment of Treatment Resistant Depression and other detrimental mental illnesses, with a specific focus on psychedelic-derived medicines.

The company operates at 6,000 sq. ft. medical treatment facility in Nova Scotia, Canada, located next to the Hants Emergency Hospital, with a Controlled Substances laboratory, and 18 treatment rooms dedicated to providing psychedelic-assisted psychotherapy.



6,000 sq. ft. medical treatment centre in Nova Scotia, Canada operated by Halucenex

On receipt of its Controlled Drugs and Substances Dealer's License (**Dealer's Licence**) which is currently pending, Halucenex will apply to commence a phase 2 clinical trial. The Dealer's Licence will allow Halucenex to possess and conduct research and development and clinical studies on psychedelic substances including LSD, psilocybin and MDMA. Halucenex's phase 2 clinical trial is expected to commence in Q3 2021. Halucenex will also seek an amendment to the Dealer's Licence to produce, package/assemble, sell, transport, import and export psychedelic substances (**Dealer's Licence Amendment**). Notwithstanding the company is able to undertake activities in respect to other psychedelic molecules aside from psilocybin, including but not limited to LSD and MDMA, the company has undertaken not to partake in any activities in relation to these compounds until such time that the company has satisfied ASX that it is legally compliant.

Given the growing interest in psychedelic inspired medicines, there is a bottleneck in the supply chain of pharmaceutical grade psilocybin that is expected to expand as more companies enter the research domain, with clinical trial submissions testing psilocybin for a multitude of mental illnesses.



Synthetic psilocybin is preferred over naturally sourced psilocybin in a clinical settings, as naturally sourced psilocybin is known to have greater inconsistency of potency and therefore dosage. Health Canada therefore approves clinical trials only if companies have access to synthetic psilocybin to ensure consistency of dosage and purity in formulations.

In anticipation of a worsening supply shortage, Halucenex has signed a supply agreement with one of Canada's only pharmaceutical grade synthetic psychedelics manufacturers, Psygen Industries Inc., securing supply of 11.6g (11,600mg) of synthetic psilocybin for use in Phase 2 and Phase 3 clinical trials. Halucenex is currently one of approximately 11 companies to secure supply from Psygen, significantly de-risking the clinical trial timeline.

Halucenex also has an affiliation with Veterans Affairs Canada via its Strategic Adviser David Fraser, which will provide a fast track to revenue through sales into a market with significant demand and government backing.

The prevalence of PTSD among veterans is considerably higher than the general population. Veterans Affairs Canada is a government department responsible for pensions, benefits and service to war veterans. The Canadian government has budgeted over C\$25m over the next decade to support research on veteran health and spends over C\$1.1Bn annually on disability pensions.

Halucenex's short-term focus is on progressing clinical trials to assess the safety and efficacy of PAP using psilocybin to treat mental illness, with the aim of becoming a clinical drug pipeline provider, while also progressing two complementary business strategies.

Halucenex will conduct R&D to produce novel proprietary formulations of synthetic psilocybin in order to de-risk supply, increase yields for future micro and macro dosing formulations, and to open the manufacturing vertical. Alongside partners Acadia University and non-profit research organisation Mitacs, Halucenex will research methods of synthesising psilocybin in scalable quantities, with the aim of developing formulations for use in preclinical and clinical experiments.

Halucenex will also conduct R&D into the interactions between natural and synthetic psilocybin derivatives to accumulate intellectual property on the entourage effects of naturally sourced psilocybin. In partnership with Acadia University and Mitacs, Halucenex is progressing the project to gather information on organic and synthetic psychoactive molecules derived from psychedelic psilocybin mushrooms, with preliminary results from the project expected by Q2 2022.

Positioned to leverage two world-class pharmaceutical companies to provide the highest quality patient outcomes:

The proposed acquisition of Halucenex provides Creso Pharma with direct entry into the emerging psychedelic medicines market, creating a diversified natural medicines company to improve mental health and wellness. The combined group will allow Halucenex to benefit from a number of significant synergies, ultimately fast tracking the company to early revenues:

- (a) an established global distribution network with partners in the pharmaceutical space;
- (b) a cutting-edge cannabis cultivation facility fitted with infrastructure which can readily be adapted for the cultivation of natural psychedelic psilocybin mushrooms; and
- (c) an executive and management team with an excellent track record of bringing pharmaceutical products to market, and a deep understanding of pharmaceutical product development in heavily regulated environments, allowing Halucenex to progress its clinical trials and successfully commercialise.



Together, Creso Pharma and Halucenex are positioned at the forefront of innovation in the psychedelic medicines sector, headed by an accomplished operational team underpinned by experienced researchers, academics, clinicians and thought leaders in the cannabis and psychedelic medicines space.

The psychedelic medicines sector and Psychedelic-Assisted Psychotherapy (PAP)

Psychedelic-assisted psychotherapy with microdoses refers to therapeutic practices that involve the ingestion of small doses (“microdoses”) of a psychedelic drug. The aim of a microdose is to dose a small enough quantity to trigger the drug’s therapeutic benefits without the potentially disruptive effects seen at higher doses (“macrodose”), such as hallucinations.

Research into the effects of psychedelics on mental health grew between 1950 and 1960, however, for largely political reasons, research was limited from the 1970s. Growing evidence demonstrating that psychedelic medicines are safe and non-addictive when used in medical settings has sparked renewed interest in PAP. In a number of clinical trials completed in recent years, psychedelic-assisted psychotherapy has produced some significant, long-lasting clinical outcomes for individuals suffering from conditions such as addiction^v, depression^{vi}, end-of-life distress^{vii}, and Post-Traumatic Stress Disorder^{ix}.

The potential for PAP to be commercialised as an effective, safe treatment provides the solution to a growing global mental health crisis. Mental illness is significantly undertreated, with current mainstream treatments widely considered to be ineffective and with many major side effects. Previous surveys have indicated that less than half of individuals with a mental illness receive any form of treatment^x.

Due to the growing prevalence of mental illness, especially during the COVID-19 pandemic, combined with inadequate treatment options, the market for psychedelic medicines to treat mental illness is growing rapidly, with estimates valuing it at up to US\$100Bnⁱ.

Mental illness also presents a significant economic burden, with researchers projecting that without innovation in treatments such as PAP, the global economic burden is estimated to reach US\$16 trillion by 2030^{xi}.

Commentary:

Non-executive Chairman Adam Blumenthal said: *“This is a major milestone for Creso Pharma and marks our evolution into a broader based pharmaceutical business. Creso will now sell its trusted cannabis products and progress the commercialisation of a range of psychedelic-assisted psychotherapy treatments. Our entry into this market provides the Company with another lucrative vertical and an additional near term revenue stream.*

“Mental health and PTSD are becoming detrimental to our society and this has been highlighted in the last 12 months. These conditions have been exacerbated by COVID-19 and the available treatments are shown to have limited effectiveness and many side effects. Psychedelic-assisted therapy is a new alternative treatment route, which has considerable promise.

“The acquisition of Halucenex will strengthen our presence in Canada, as well as provide a number of opportunities in drug development which will inevitably lead to further new market entries and commercialisation opportunities.”



Halucenex Founder & CEO Mr Bill Fleming said: *“Halucenex is excited to be acquired by Creso and looks forward to leveraging its strategic relationships and expertise in the pharmaceutical industry. Halucenex has an early advantage in that it has applied for the Controlled Substances License, it has a laboratory for research on psychedelic compounds and a medical clinic to conduct micro and macro dose trials.*

“Our ability to design a clinical protocol and fast track a phase 2 Treatment Resistant Depression clinical trial will allow us to be one of the first companies to demonstrate the efficacy of psilocybin in Canada.”

Creso’s Strategic Advisor Mr Bruce Linton added: *“Public policy towards psychedelics is rapidly shifting and we are witnessing a massive regulatory wave which has the capacity to change the way that mental health and wellness is achieved and maintained. Through this acquisition, Creso is directly and immediately in the search for science driven outcomes.”*

“Vision and discipline came together in making this acquisition.”

Key Deal Terms:

Consideration:

- \$500,000 in cash (Cash Consideration)
- 29,251,795 Creso Pharma shares (Consideration Shares)
- 17,551,077 Creso Pharma performance shares that will convert into fully paid ordinary shares if the Dealer’s Licence Amendment within 12 months of settlement of the Acquisition (Consideration Performance Shares)
- The Consideration Shares and any Creso shares issues on conversion of the Consideration Performance Shares will be subject to voluntary escrow for 6 months following settlement.

Conditions Precedent:

Settlement of the Acquisition is conditional satisfaction of conditions precedent, including:

- Creso completing financial legal and technical due diligence within 45 days of execution
- Creso obtaining all necessary shareholder and regulatory approvals, including without limitation approval for the issue of the Consideration Shares and Consideration Performance Shares (or Additional Consideration Shares where applicable) to the vendors (or their nominees);
- Creso and Halucenex obtaining all third-party approvals and consents necessary to lawfully complete the Acquisition.

Other key terms

- Creso will advance Halucenex \$250,000 as a loan for the sole purpose of funding Halucenex’s operations prior to settlement.
- Creso has agreed to apply at least a further \$1,000,000 in funding to Halucenex business during the 12 months period following settlement.
- The vendors have a right to nominate a director to the board of Creso (as a non-executive director) up until three (3) months following settlement. The vendors have not yet nominated a nominee director.

The Company intends to seek shareholder approval for the issue of the Consideration Shares and Consideration Performance Shares at the Company’s upcoming annual general meeting expected to be held in April 2021. Full terms of the Consideration Performance Shares will be included in the relevant notice of meeting.



-Ends-

Authority and Contact Details

This announcement has been authorised for release by the Creso Board

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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

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.



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- i Canaccord Genuity US Equity Research – Biotechnology Industry Update - Psychedelic-derived medicines and therapies: a follow-up primer
- ii Credence Research Post-Traumatic Stress Disorder Therapeutics Market - Growth, Future Prospects and Competitive Analysis, 2018-2026
- iii Smetanin 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.
- iv Lim et al. (2008). A new population-based measure of the burden of mental illness in Canada. *Chronic Diseases in Canada*, 28: 92-8.
- v Johnson, M et al. (2014). 5-HT_{2A}R agonist psilocybin in the treatment of tobacco addiction. *Journal of Psychopharmacology*, 28-11:983-992.
- vi Carhart-Harris et al. (2016). Psilocybin with psychological support for treatment-resistant depression. *The Lancet*, 3-7:619-627
- vii Griffiths, R. R. et al. (2016). Psilocybin produces substantial and sustained decreases in depression and anxiety in patients with life-threatening cancer: A randomized double-blind trial. *Journal of psychopharmacology*, 30(12), 1181-1197
- viii Ross et al. (2016). Rapid and sustained symptom reduction following psilocybin treatment for anxiety and depression in patients with life-threatening cancer: a randomized controlled trial. *Journal of Psychopharmacology*, 30-12:1165-1180
- ix M.C. Mithoefer, T.M. Wagner, A.T. Mithoefer, L. Jerome, R. Doblin, The safety and efficacy of \pm 3,4-methylenedioxymethamphetamine-assisted psychotherapy in subjects with chronic, treatment-resistant posttraumatic stress disorder: the first randomized controlled pilot study, *J. Psychopharmacol.* 25 (4) (2011) 439-452
- x SAMSHA. National Survey on Drug Use and Health. 2007 from <http://www.oas.samhsa.gov/NSDUH/latest.htm>
- xi <https://www.sbs.com.au/news/the-burden-of-mental-health-could-cost-23-trillion-by-2030#:~:text=The%20burden%20of%20mental%20illness,enough'%20according%20to%20the%20report>