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Halucenex Life Sciences Inc. to progress US market entry strategy for botanical psilocybin products and compounds

Highlights:

- **Consultancy agreement with HeteroGeneity, LLC to assist with US expansion for Halucenex's botanical psilocybin products**
- **HeteroGeneity is a leading consultancy focused on assisting companies achieve regulatory approval for new drug developments for use in the USA**
- **Both parties to collaborate on requirements for potential US market launch**
- **Defined strategy will allow Halucenex to pursue FDA approval for botanical psilocybin products and commence licencing discussions with large pharma**
- **Agreement adds to leading partners Halucenex has assembled ahead of its phase II clinical trial – providing considerable competitive advantage**
- **US psychedelic drug market expected to total US\$6.8Bn by 2027ⁱ – highlights a significant opportunity for Creso Pharma**

Creso Pharma Limited (ASX: CPH, FRA:1X8) ('Creso Pharma' or 'the Company') is pleased to advise that target acquisition company Halucenex Life Sciences Inc. ("Halucenex") has entered into a consultancy agreement ("Agreement") with leading US based scientific consultancy HeteroGeneity, LLC ("HeteroGeneity") to progress a US market entry strategy for the potential use and licencing of the Company's botanical psilocybin products and compounds.

HeteroGeneity is a scientific management organisation based in Washington DC. It provides strategic and technical assistance to clients conducting R&D and commercialisation of drugs, biologics and medical devices for the US and Canadian markets.

The group specialises in the regulation, policy and science of complex, heterogeneous mixtures and addresses novel use areas for traditional medicine practice and naturally of historically complex products.

HeteroGeneity is at the forefront of regulation in North America and has been instrumental in assisting a number of companies achieve New Drug Approval Applications through the Food and Drug Administration (FDA) for the US market.

Under the Agreement, both parties will conduct a technology assessment to progress a development plan for a new botanical drug under pharmaceutical development for the US market. This will include advisory around clinical indications, regulatory status of proposed ingredients, sourcing, manufacturing and formulation, compilation of supporting data and intellectual property considerations amongst other initiatives. HeteroGeneity shall be compensated on a hourly basis, and may be terminated without cause by either party upon giving 30 days written notice.



The Agreement marks an important first step in the Company's US market entry strategy. HeteroGeneity will assist the Creso Pharma and Halucenex with any required FDA regulatory approvals, and will enable Creso to commence discussions with large-scale pharmaceutical companies around licencing agreements for its extracts and psychedelic compounds.

The psychedelic therapeutic drug market in the US is expected to reach a total value of US\$6.7Bn by 2027¹ and represents a very lucrative opportunity for Creso Pharma. Ahead of the pending phase II clinical trial (refer ASX announcement: 15 March 2021), Halucenex has assembled a market leading team of consultants and strategic partners, which will provide it with a considerable competitive advantage as it progresses its clinical trials and US market entry, subject to necessary legislative reform.

Commentary:

Halucenex Founder and CEO Mr Bill Fleming said: *"The US is set to become the most important and lucrative market for psychedelic medicines as an alternative treatment, so it is imperative that Halucenex begin to plan its market entry now. We are very confident that HeteroGeneity are the right partner to assist us moving forward, given their tremendous track record with FDA approvals for new drugs, medical devices and treatments.*

"We look forward to working with the group to establish the immediate requirements for the US market. We anticipate that the data from our pending phase II clinical trial will play a major role in this and look forward to being able to update shareholders on the commencement of this initiative in the coming months."

Non-executive Chairman Adam Blumenthal said: *"Creso's Board and management are very pleased that Halucenex is taking steps forward in the early stages to progress a US market entry.*

"Having centralised operations in Nova Scotia will provide Halucenex with considerable advantages when undertaking the steps required to progress regulatory approvals and potential discussions with large pharmaceutical groups for the licensing of the group's psilocybin extracts and compounds."

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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

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.prnewswire.com/news-releases/multi-billion-dollar-market-forecast-in-psychedelic-therapeutics-301151890.html>