

## Psyence Signs Letter of Intent with Australian CRO iNGENū

**Vancouver, British Columbia, January 08, 2023** – [Psyence Group Inc \(CSE:PSYG | OTCQB: PSYGF\)](#), a life science biotechnology company pioneering the use of natural psilocybin in mental health and well-being, today announced that it has signed a Letter of Intent (LOI) with Contract Research Organisation (CRO) iNGENū CRO Pty Ltd (iNGENū) to execute Psyence’s strategy of market leading clinical development of psilocybin within palliative care. iNGENū is a globally focused CRO with extensive experience in working in the psychedelic pharmaceutical drug development and clinical research industry. iNGENū will be responsible for jointly designing the Phase IIb clinical trial to be conducted in Australia, in compliance with global standards.

The LOI centres around Psyence’s global development and regulatory strategy of its licensed compound PEX010 in palliative care in Phase II clinical trials. The prospective cooperation and trial would potentially reduce Psyence’s timeline for starting a Phase III registrational clinical trial.

*“We are intent on progressing our clinical research strategy as expeditiously as possible and Australia’s highly supportive clinical research and regulatory environment has made it a key early research destination for Psyence,” said **Dr. Neil Maresky, Chief Executive Officer of Psyence.** “Engaging an experienced and trusted CRO is critical to the success of our mission and we are delighted to sign this LOI with iNGENū in this regard.”*

***Dr. Sud Agarwal, Chief Executive Officer of iNGENū** commented “our team is pleased that Psyence has contracted iNGENū with their clinical development needs and we look forward to working together to design and conduct trials with our partner investigators here in Australia. We are impressed with both their clinical team and their wider team driving this exciting program at the forefront of palliative care.”*

The Phase IIb study will be carried out by iNGENū after the application process has been completed in Australia. The planned randomised double-blind study, which will take place in Melbourne, will evaluate the use of psilocybin assisted psychotherapy vs psychotherapy alone. It will use FDA-recommended primary endpoints to test natural psilocybin (PEX010) in over 75 patients with adjustment disorder due to a recent terminal cancer diagnosis. Upon successful completion of the study, Psyence aspires to conduct a multinational Phase III registrational study.

### **About Psyence Group, Inc.**

Psyence is a life science biotechnology company listed on the Canadian Securities Exchange (CSE: PSYG) and quoted on the OTCQB (OTCQB: PSYGF), with a focus on natural psychedelics. The Psyence Biomed Division works with natural psilocybin products for the healing of psychological trauma and its mental health consequences in the context of palliative care. Our name “Psyence” combines the words psychedelic and science to affirm our commitment to producing psychedelic medicines developed through evidence-based research. Informed by nature and guided by science, we built and operate one of the world’s first federally licensed commercial psilocybin mushroom cultivation and production facilities in Southern Africa. Our team brings international experience in both business and science and includes experts in mycology, neurology, palliative care, and drug development. We work to develop advanced natural psilocybin products for clinical research and development. Our key divisions, Psyence Production, Psyence Therapeutics and Psyence Function, anchor an international collaboration, with

operations in Canada, the United Kingdom, Southern Africa, and a presence in the United States and Australia.

Learn more at [www.psyence.com](http://www.psyence.com) and on [Twitter](#), [Instagram](#) and [LinkedIn](#).

### **About iGENŪ CRO Pty Ltd**

iGENŪ is a globally focused Contract Research Organization working exclusively in the cannabinoid and psychedelic space. Our core values: subject matter expertise – globally unmatched expertise in psychedelic drug development; client-centric culture – a highly transparent and collaborative style of partnering with sponsors; and an agile and lean approach to drug development. The Australian advantage is the ability to perform high quality (FDA-eligible) clinical trials prior to opening an IND, accessing 43.5% research and development rebate from the Australian Government, and rapid start-up of clinical trials in under 12 weeks.

Learn more at [www.ingenucro.com.au](http://www.ingenucro.com.au)

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### **FORWARD LOOKING STATEMENTS PSYENCE**

*Certain statements in this news release related to Psyence Group Inc and its subsidiaries (collectively the "Company") are forward-looking statements and are prospective in nature. Forward-looking statements are not based on historical facts, but rather on current expectations and projections about future events and are therefore subject to risks and uncertainties which could cause actual results to differ materially from the future results expressed or implied by the forward-looking statements. These statements generally can be identified by the use of forward-looking words such as "may", "should", "could", "intend", "estimate", "plan", "anticipate", "expect", "believe" or "continue", or the negative thereof or similar variations. Forward-looking statements in this news release include statements regarding the future success of the partnership between iGENŪ, the receipt of all such approvals as may be required to commence the clinical trials referred to in this news release, the procurement of the necessary FDA approvals to execute on Psyence's strategy, the expediting of a Phase III registrational clinical trial, and Psyence's ability to deliver its intended drug product to patients. These forward-looking statements are based on a number of assumptions, including the assumptions that Psyence will obtain all such regulatory and other approvals as may be required to pursue its clinical trials on the drug product referred to in the news release, the results of such clinical trials will be positive, and Psyence will be able to commercialize Filament's natural psilocybin drug candidate, PEX010 (25 mg). There are numerous risks*

*and uncertainties that could cause actual results and the Company's plans and objectives to differ materially from those expressed in the forward-looking information. These risks and uncertainties include demand for the Company's securities being less than anticipated, fluctuations in the price the Company's common shares, and the Company not raising the amount expected, or any funds at all. Actual results and future events could differ materially from those anticipated in such information. These and all subsequent written and oral forward-looking information are based on estimates and opinions of management on the dates they are made and are expressly qualified in their entirety by this notice. Except as required by law, the Company does not intend to update these forward-looking statements.*

*The Company makes no medical, treatment or health benefit claims about the Company's proposed products. The efficacy of psilocybin, psilocybin analogues, or other psychedelic compounds or nutraceutical products remains the subject of ongoing research. There is no assurance that the use of psilocybin, psilocybin analogues, or other psychedelic compounds or nutraceuticals can diagnose, treat, cure or prevent any disease or condition. Vigorous scientific research and clinical trials are needed. The Company has not conducted clinical trials for the use of its proposed products. Any references to quality, consistency, efficacy, and safety of potential products do not imply that the Company verified such in clinical trials or that the Company will complete such trials. If the Company cannot obtain the approvals or research necessary to commercialize its business, it may have a material adverse effect on the Company's performance and operations.*