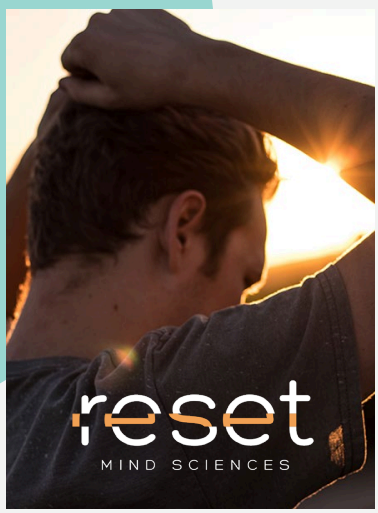
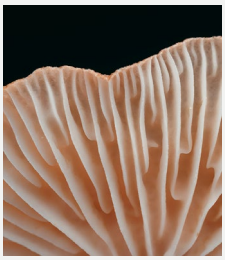
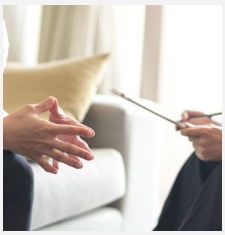
ASX ANNOUNCEMENT

15 February 2023

Ethics approval granted for psilocybin clinical trial







Highlights:

- Reset Mind Sciences receives ethics approval to conduct clinical trial into efficacy and safety of psilocybin assisted therapy involving family members for patients with treatment resistant major depressive disorder
- Trial focused on development and refinement of best practice psychotherapy protocols to accompany administration of psilocybin
- Trial to be sponsored by Reset Mind Sciences with leading academic and consultant psychiatrist Professor Sean Hood (University of Western Australia) as Principal Investigator
- Recruitment expected to commence in the second quarter of 2023 with the trial expected to take approximately 12 months to complete
- Trial takes on heightened relevance and significance following the TGA's recent decision to down-schedule psilocybin in defined circumstances for use with treatment resistant depression

Little Green Pharma Ltd (ASX: LGP, "**LGP**" or the "**Company**") is pleased to announce its wholly owned subsidiary and operator of LGP's psychedelics business, Reset Mind Sciences Limited ("**Reset**") has received Human Research Ethics Committee ("**HREC**") approval to conduct its proposed twelve-month, single-centre, randomised, open-label, parallel group (2-arm), superiority clinical trial ("**Clinical Trial**" or "**Trial**") into the efficacy and safety of psilocybin-assisted psychotherapy ("**PAP**") involving family members compared to standard PAP for adults with treatment resistant major depressive disorder. The grant of the HREC approval for the Clinical Trial is the result of a more than 18-month development and approval process in cooperation with key clinical trial personnel from University of Western Australia and Edith Cowan University.

The Clinical Trial builds on the increasing body of research globally into the use of psilocybin to treat depressive related conditions by incorporating key family members into the preparatory and integration therapy sessions that precede and follow the psilocybin administration sessions. The Trial has taken on added significance and relevance given the TGA's announcement on 3 February 2023 that it had changed the classification of psilocybin within certain defined parameters for the treatment of Treatment Resistant Depression from 1 July 2023. A copy of the media release is available here: https://www.tga.gov.au/news/media-releases/change-classification-psilocybin-and-mdma-enable-prescribing-authorised-psychiatrists

The Trial allows Reset to test and refine best practice psychotherapy protocols to accompany administration of psilocybin to trial participants. Recruitment for the Trial is anticipated to commence in the second quarter of 2023 with the trial expected to run for approximately 12 months. The trial will include 60 participants and will be conducted at the Harry Perkins Institute of Medical Research in Perth, Western Australia in conjunction with Fiona Stanley Hospital. It is expected to be the first clinical trial to be conducted in Western Australia using psilocybin.

Reset Mind Sciences Chief Executive Officer, Shaun Duffy, commented:

"We're focused on testing and refining psychotherapy protocols and developing a network of clinicians with real world experience in the administration of psychedelic assisted psychotherapy. They're our primary objectives here and we believe the work has taken on even more importance in the wake of the recent decision by the TGA.

"The trial will be one of the first psilocybin assisted therapy trials in Australia and we trust it will contribute meaningfully to the clinical evidence supporting the use of psilocybin and other psychedelics for the treatment of chronic mental illness in Australia.

"Given we are investigating the condition allowed by the TGA for prescription of psilocybin from 1 July 2023, we anticipate the clinical evidence we obtain will be highly instructive in the treatment of patients under the new regime announced by the TGA."

Overview of key Clinical Trial *personnel*

The Principal Investigator for the Clinical Trial is Professor Sean Hood, Head of the Psychiatry Division at the University of Western Australia: https://www.uwa.edu.au/Profile/Sean-Hood. Professor Hood will have oversight of responsible governance and treatment delivery for the trial.

Professor Hood said

"This clinical trial is so timely with its heavy emphasis on the psychotherapy protocols to accompany administration of psilocybin. We have put more than 18 months of considered work into the development of our protocols and put our therapy team through an intensive training regime. We believe these are the standards that are required for the responsible and professional administration of psychedelic drugs."

Professor Hood will be supported by Co-Investigator, Dr Stephen Bright, a trained psychologist and Senior Lecturer of Addiction at Edith Cowan University in Western Australia: https://www.ecu.edu.au/schools/medical-and-health-sciences/our-staff/profiles/senior-lecturers/dr-stephen-bright.

Dr Bright said

"Reset's Clinical Trial will provide an ideal environment to scientifically validate protocols for the delivery of psilocybin-assisted psychotherapy. I can't stress enough the important role that psychotherapy plays in ensuring this novel treatment is safe and effective. We have assembled an outstanding therapy team for this Trial and I'm looking forward to the opportunity to work with them."

The Trial's Clinical Supervisor is Renee Harvey, a trained clinical psychologist with prior experience in psilocybin clinical trials, including as a patient therapist in the Imperial College of London psilocybin clinical trial: https://www.linkedin.com/in/renee-harvey-42a9b543/?originalSubdomain=au

Mental illness in *Australia*

Since COVID-19, the rate of mental illness and behavioural conditions in Australia and globally have been increasing, with the full impact on COVID-19 on mental health conditions still unknown. Today, mental illness is the most common chronic illness in Australia, with 1 in 5 Australians having a mental or behavioural condition (up 20% from 2014/15) and 10.4% of Australian having depression or feelings of depression.[1]

[1]https://www.abs.gov.au/statistics/health/mental-health/mental-health/2017-18

Proposed Reset *demerger*

The proposed demerger of Reset from the LGP Group remains a priority and following the receipt of HREC approval for the Clinical Trial and the recent announcement by the TGA, the demerger will proceed as a priority. The ultimate timing of the demerger is subject to prevailing market conditions. Upon the demerger Reset will reimburse LGP for certain costs it has incurred prior to the demerger.

Reset is currently developing a business model designed to advantageously position the company for the evolution of the Australian psychedelics industry, with Reset currently undertaking concurrent mushroom-based psilocybin product development and clinical trial and research streams to enable both product and service delivery through an integrated supply pathway.

ENDS
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About Little Green Pharma

Little Green Pharma is a global, vertically integrated and geographically diverse medicinal cannabis business with operations from cultivation and production through to manufacturing and distribution.

The Company has two global production sites for the manufacture of its own-branded and white-label ranges of GMP-grade medicinal cannabis products, being a 21,500m^2 cultivation and 4,000m^2 GMP manufacturing facility capable of producing over 30 tonnes of medicinal cannabis biomass per annum located in Denmark (EU) and an indoor cultivation and manufacturing facility located in Western Australia capable of producing ~3 tonnes of medicinal cannabis biomass per annum.

Little Green Pharma products comply with all required Danish Medicines Agency and Therapeutic Goods Administration regulations and testing requirements. With a growing range of products containing differing ratios of active ingredients, Little Green Pharma supplies medical-grade cannabis products to Australian, European and overseas markets.

The Company has a strong focus on patient access in the emerging global medicinal cannabis market and is actively engaged in promoting education and outreach programs, as well as participating in clinical investigations and research projects to develop innovative new delivery systems.

For more information about Little Green Pharma go to: www.littlegreenpharma.com

Help us be Green

LGP investors are encouraged to go paperless and receive Company communications, notices and reports by email. This will ensure efficient communication during COVID-19 while also helping to reduce our costs and environmental footprint.

To easily update your communication preferences, visit: www.computershare.com.au/easyupdate/lgp