

## ASX ANNOUNCEMENT

6 February 2023

# Psilocybin and MDMA down-scheduled



### *LGP's psychedelics subsidiary Reset Mind Sciences welcomes the TGA's decision to down-schedule psilocybin and MDMA*

Little Green Pharma (**ASX: LGP**) and its psychedelics focused subsidiary Reset Mind Sciences Limited ("**Reset Mind Sciences**") welcome Friday's decision by the Therapeutic Goods Administration ("**TGA**") to change the classification of psilocybin and MDMA to allow prescribing by authorised psychiatrists.

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 announcement means Australia will become the first market in the world to recognise psychedelics as medicines and paves the way for the use of psilocybin for the treatment of treatment resistant depression and MDMA for PTSD outside of a clinical trial environment from 1 July 2023.

The TGA's decision to re-classify psilocybin and MDMA has come significantly earlier than expected by industry, given the TGA's decision in late December 2021 not to reclassify and limit use to clinical trials only. However, the unexpected change uniquely positions Reset compared to other psychedelic companies in Australia given both its Schedule 9 licence, authorizing it to cultivate and supply psilocybin, and its impending clinical trial, enabling Reset to validate its treatment protocols for the use of psilocybin in connection with treatment resistant depression. These developments now allow Reset to accelerate and implement its commercialisation plans far earlier than expected.

Reset Mind Sciences CEO Mr. Shaun Duffy said, "*The announcement by the TGA is truly groundbreaking in the field of psychedelics and I welcome their decision. There is a significant body of research emerging in Australia and globally for the use of psychedelics to treat mental health conditions and this decision allows the use of these drugs for the mental health conditions that have demonstrated the most potential in the research.*"



Reset Mind Sciences is in the advanced stages of preparations for a Perth based clinical trial using psilocybin for treatment resistant depression, the condition the TGA has identified as permissible for treatment under its prescribed parameters.

Mr. Duffy said, *"We have put more than 18 months of detailed planning into our trial with a focus on testing, refining and developing the therapy protocols that go along with the administration of psilocybin. This is a specialised field of expertise in itself that should not be underestimated and our trial provides an environment to optimise our protocols. We have assembled an outstanding team of therapists that are trained and ready to go once we finalise the ethics approval process. Given the comments from the Ethics Committee to date we hope and expect that's not far away."*

The trial's Principal Investigator is the University of Western Australia's Professor Sean Hood who will have oversight of responsible governance and treatment delivery.

*"It is incumbent on the industry to proceed in a professional and responsible manner with this treatment and ensure those administering it have the necessary skills"* added Mr Duffy.

In addition, Reset Mind Sciences is in the final stages of commissioning construction of a bespoke mushroom cultivation facility which is expected to be on site at LGP's existing cannabis cultivation facility in the coming weeks. Reset is one of a very limited number of Australian companies legally permitted to cultivate psilocybin containing mushrooms. Reset's objective is to be able to produce GMP grade psilocybin from its mushrooms as soon as possible.

Mr. Duffy added, *"Reset is fortunate that its clinical trial indication focus on treatment resistant depression matches the TGA's psilocybin policy, as well as deciding to obtain a Schedule 9 supply and manufacturing licence in 2019 to enable progress of its inhouse psilocybin production capability. We believe the advanced stage of Reset's treatment ecosystem puts the company in a strong leadership position for this significant therapeutic development."*

*"We're still working through the full implications of the TGA's decision for our strategy moving forward but suffice to say it's a very positive development for us and will result in an acceleration of our plans."*

Little Green Pharma has previously announced its intention to demerge Reset by way of an in-specie distribution of its current ownership out to its shareholder base. If approved by LGP shareholders, the effect would be that eligible LGP shareholders on a certain record date (to be determined) would receive a separate direct shareholding in Reset Mind Sciences and the opportunity to invest additional funds into it.

*"Given this regulatory development and that Reset is on the precipice of becoming operational on both the clinical trial and cultivation fronts, we believe the time is right to move ahead with the demerger of Reset Mind Sciences from Little Green Pharma into a standalone dedicated psychedelics company."*

ENDS  
BY ORDER OF THE BOARD



**Alistair Warren**  
Company Secretary

For further information please contact:

**Alistair Warren**  
**Company Secretary**  
Little Green Pharma  
E: [a.warren@lgp.global](mailto:a.warren@lgp.global)  
T: +61 8 6280 0050

**Shaun Duffy**  
**Chief Executive Officer**  
Reset Mind Sciences  
E: [s.duffy@lgp.global](mailto:s.duffy@lgp.global)  
T: +61 (0)404 094 384

**Fleta Solomon**  
**Managing Director**  
Little Green Pharma  
E: [f.solomon@lgp.global](mailto:f.solomon@lgp.global)  
T: +61 8 6280 0050



### 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<sup>2</sup> cultivation and 4,000m<sup>2</sup> 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](http://www.littlegreenpharma.com)

For more information about Reset Mind Sciences go to: <https://www.resetmind.com.au/>

### 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.

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