



ASX Release

19 April 2017

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ASX Code:

ZLD

Ordinary Shares:

754,841,934

Options:

48,000,000

6,000,000 (\$0.04 - 6/2/2020 -
subject to vesting conditions)
2,000,000 (\$0.04 - 6/2/2020)
40,000,000 (\$0.03125-17/11/2021)

Clinical Research Programme to Expand to Include Autism Spectrum Disorder

- **Zelda Therapeutics will partner with Chilean non-profit group Fundación Daya, further expanding its Chilean clinical trial programme to include autism as well as insomnia and eczema**
- **The global market for autism diagnosis and treatments is expected to grow to US\$412.7 million in 2019**
- **Leverages relationship with ASX-listed AusCann which through its joint venture in Chile, DayaCann, will supply high quality medical cannabis for the trial**
- **Chile has a robust regulatory environment and provides a very cost effective location to conduct clinical trials**

The Board of **Zelda Therapeutics Ltd (ASX: ZLD, Zelda or the Company)** is pleased to announce it has expanded its clinical trial programme in Chile to include Autism Spectrum Disorder (autism). Zelda will work together with Chilean non-profit patient advocate group Fundación Daya, leveraging their clinical experiences with autism patients which demonstrates solid anecdotal evidence of positive quality of life outcomes using cannabinoid-based therapy.

Autism is a lifelong development disability characterized by impairments in social communication and interactions¹. The disability is of major global significance, with prevalence increasing by 6-15% each year². Statistics reveal 1% of the world population currently suffers from autism², on this basis, Australia alone is estimated to have 230,000 people suffering from the disability. The global market for autism diagnosis and treatments is expected to grow to US\$412.7 million by 2019³.

The legal framework in Chile recognizes the importance of medical cannabis, allowing its production under strict regulatory controls for the treatment of medical conditions. The country also provides a cost-effective location for Zelda to conduct clinical trials. Furthermore, Zelda through its relationship with AusCann Group Holdings Ltd (ASX:AC8) will leverage Auscann's Chilean joint-venture DayaCann to supply high quality medical cannabis for the autism trial.

Fundación Daya have extensive experience over a number of years in using medical cannabis to treat patients diagnosed with autism. Zelda will leverage this data and access to patients to develop robust clinical trials and conduct its research under rigorous and controlled clinical conditions, using medicinal cannabis formulations already known to have an effect in sufferers of autism.

The recent successful capital raising has ensured Zelda has sufficient financial resources to be able to capitalise on new opportunities such as this, which expands its clinical programme, diversifying risk and maximising value creation potential for shareholders.

Subject to regulatory approvals being obtained, Zelda expects the trial will commence in the second half of 2017, with trial protocols already being developed. The Company expects the trial to be conducted over a period of 3-6 months.

Successful results will allow the Company to immediately commence the product registration process to sell clinically approved products in the Chilean market. This provides a clear pathway to potential revenue generation from Chile and other South American markets as early as 2018.

Zelda Therapeutics is focused on using its global strategic partnerships to bring together experts in the medical cannabis field to clinically prove the benefits of medical cannabis and deliver new cannabis based therapies to patients in need.

Harry Karelis, Executive Chairman said *“Our recent capital raising provides us with increased flexibility to pursue this new indication. Autism affects whole families and any safe, effective and affordable treatment is greatly appreciated by patients. Fundación Daya have extensive positive experience in treating patients using cannabis-based medicines. Our investment into conducting a rigorous and controlled clinical trial paves the way for product registrations next year significantly improving patient access to a novel form of treatment. Our intention would be to replicate this trial in other key jurisdictions to rapidly improve patient access in other jurisdictions.”*

Dr Gisela Kuester, Director, Clinical Research, Fundación Daya Chile said: *“We have been treating numerous patients suffering from varying degrees of autism to date with very positive outcomes. We welcome the involvement of Zelda in conducting what we believe is the first rigorous trial using cannabinoids to treat the symptoms of this condition. We are very excited about the prospects to improve the range of treatments available to patients and their families”*

Tim Slate
Company Secretary

About Zelda Therapeutics (www.zeldatherapeutics.com)

Zelda Therapeutics (“Zelda”) is an Australian-based bio-pharmaceutical company that has secured exclusive, global access to an extensive set of human data related to medicinal cannabis based formulations and treatment protocols. This human data has been generated over several years by a California-based group (*Aunt Zelda’s*) that has a very high profile within the USA and a growing international profile based upon its deep knowledge of the scientific rationale for certain cannabis-based formulations and protocols to treat a variety of medical conditions.

Zelda has embarked on a programme of human clinical trials initially in sleep disorder (insomnia) and eczema indications.

In addition, Zelda is building a pre-clinical research portfolio targeting cancer. It has partnered with the world’s leading cancer cannabis researchers at Complutense University Madrid in Spain to conduct certain pre-clinical work testing cannabis-based formulations known to have an effect in humans in order to generate data packs in a form expected by regulators and the pharmaceutical industry. A similar programme is in place with the Australian Telethon Kids Institute targeting paediatric brain cancer and Curtin University targeting pancreatic cancer.

About Fundación Daya (www.fundaciondaya.org)

Fundación Daya is Chile’s pre-eminent non-profit patient advocacy group working with medicinal cannabis. The organization conducts research into alternative therapies and advises on the development of public health policies. There are a number of clinical research projects that the organization is involved in together with municipalities, public hospitals, universities and a laboratory. These projects seek to scientifically validate the use of medical cannabis for specific disease targets.

¹ <https://www.autismspectrum.org.au>

² <http://www.autism-society.org/what-is/facts-and-statistics/>

³ <https://www.bccresearch.com/market-research/healthcare/diagnosis-therapies-autism-spectrum-disorders-markets-report-hlc181a.html>