



More people in Australia die from accidental drug overdoses than in road accidents. More alarming is that prescription painkillers cause two and a half times more deaths than illicit drugs. This is a major concern considering one in five Australians live with chronic pain.⁽¹⁾

According to a 2017 report from Australia's National Drug and Alcohol Research Centre, the rate of accidental opioid deaths has more than doubled among Australians aged 35 to 44 since 2007. Seventy per cent of these deaths involved strong prescription painkillers.⁽¹⁾

What are "opioids"?

Opioids are a class of drug naturally found in the opium poppy plant. Some prescription opioids are sourced directly from the plant, while others are synthesized by chemists.

Prescription opioids are used as medicines to relieve severe and chronic pain⁽²⁾ while heroin is one of the world's most dangerous illegal opioids.

Opioids can also make people feel very relaxed and "high" - which is why they are sometimes used for non-medical reasons. This is dangerous because opioids can be highly addictive, and overdoses and deaths are common.

Prescription Opioids

Opioids are best used for acute pain management, to manage severe pain after surgery, injuries or burns, pain from problems such as kidney stones, gallbladder stones, pancreatitis and heart disease, childbirth and end of life care.⁽⁵⁾

Common types of prescription opioids include hydrocodone (Vicodin®), oxycodone (OxyContin®, Percocet®), oxymorphone (Opana®), morphine (Kadian®, Avinza®), codeine and fentanyl.⁽²⁾

Australia currently ranks eighth internationally on the numbers of defined daily doses of prescription opioids per million population. In the USA, opioid analgesics are now the most commonly prescribed class of medications.⁽⁴⁾

Prescription Opioids in Australia

In Australia, all strong opioid medications are classified under Schedule 8 of the Therapeutic Goods Act, which limits the prescription period to two months.⁽⁵⁾

In 2014, almost 3 million people in Australia were prescribed at least one opioid under the Pharmaceutical Benefits Scheme (PBS) or Repatriation PBS (RPBS). Since the end of 2009, prescriptions have increased, from about 10 million to 14 million annually.⁽⁴⁾

How do prescription opioids affect the brain?

Opioids bind to and activate opioid receptors on cells located in many areas of the brain, spinal cord, and other organs in the body, especially those involved in feelings of pain and pleasure. When opioids attach to



these receptors, they block pain signals sent from the brain to the body and release large amounts of dopamine throughout the body. This release can strongly reinforce the act of taking the drug, making the experience highly addictive.⁽²⁾

What do we know about the opioid crisis?

Rates of prescription opioid overdose, including accidental overdose, are at record levels in Australia and internationally.⁽⁴⁾

Prescription opioid deaths in Australia now exceed heroin deaths by 2-2.5 times.

Between 2011 and 2015 there were 2,145 deaths associated with prescription opioids such as oxycodone, morphine, codeine, fentanyl, tramadol and/or pethidine and 985 deaths due to heroin.

Prescription opioid deaths were involved in more than 70% of drug-related deaths in Australia in 2017⁽⁵⁾ with the highest rates occurring in people over 30 years of age.⁽⁴⁾

How did this happen?

One of the contributing factors to the current crisis has been 'indication creep'. This refers to the use of prescription opioids to treat an expanding range of chronic pain indications. This has occurred despite limited evidence of improved efficacy or safety in many of these patients.

Increasing use of opioids is also driven by the lack of alternatives that are as effective for treatment of chronic pain conditions.⁽⁴⁾

The combination of poor health outcomes due to over-dosing and drug addiction, over-prescription and illicit use has resulted in opioid-related deaths surpassing the national annual road toll.⁽⁵⁾

Zelda partners with St Vincent's Hospital for opioid reduction study

Zelda and St Vincent's Hospital Melbourne have partnered to assess the effectiveness of medical cannabis to reduce the use of opioids in patients with chronic non-cancer pain.

The trial is a 20-patient study with potential to expand to a larger trial depending on results. The protocol is double-blinded, randomised and placebo-controlled. Medicinal cannabis will be sourced from a manufacturer in Europe and produced to pharmaceutical GMP grade.

A successful outcome to this trial could assist patients who have become dependent on opioids transition to less harmful medications to treat their chronic pain. Zelda would aim to supply these medicines to Australian patients via specialists registered under the Authorised Prescriber Scheme.

The clinical trial protocols are being finalised and are expected to be lodged with the human ethics committee and subject to approval, the trial is expected to commence in late 2018.



ZELDA THERAPEUTICS (ASX: ZLD)

Zelda Therapeutics Ltd (“Zelda”) is an Australian-based bio-pharmaceutical company that is focused on developing a range of cannabinoid-based formulations for the treatment of a variety of medical conditions. The Company has partnered with world renowned researchers and organisations, and has a two-pronged strategy comprising:

- A human clinical trial programme focused on insomnia, autism, chronic pain and eczema with activities in Australia, Chile and the USA.
- A pre-clinical research programme examining the effect of cannabinoids in breast, brain and pancreatic cancer as well as research examining the potential for cannabinoids to treat diabetes-associated cognitive decline.

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¹ANZCA Media Release 2018, “Australia’s escalating opioid use focus of pain forum”. Available from <http://www.anzca.edu.au/communications/media/media-releases-2018/australia-s-escalating-opioid-use-focus-of-pain-fo>

²United States National Institute On Drug Abuse, June 2018, “Prescription Opioids”. Available from <https://www.drugabuse.gov/publications/drugfacts/prescription-opioids>

³Western Alliance, February 2018, “Prescription opioids – understanding recent changes to Australian regulations”. Available from <https://www.westernalliance.org.au/2018/02/prescription-opioids-understanding-recent-changes-to-australian-regulations-4>

⁴Australian Government, Department of Health, 23 May 2018, “Consultation: Prescription strong (Schedule 8) opioid use and misuse in Australia – options for a regulatory response”. Available from <https://www.tga.gov.au/consultation/consultation-prescription-strong-schedule-8-opioid-use-and-misuse-australia-options-regulatory-response>

⁵ABC News, 5 February 2018, “Why better pain management techniques are essential to solving the opioid crisis”. Available from <http://www.abc.net.au/news/2018-02-05/fixing-pain-management-could-help-us-solve-opioid-crisis/9396826>