



# iX Biopharma Ltd

Presentation for Phillip Securities – Jan 2020

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# AGENDA



- 1) Company Overview
- 2) WaferiX Technology
- 3) Products Pipeline
- 4) Summary



# COMPANY OVERVIEW

# Company Profile

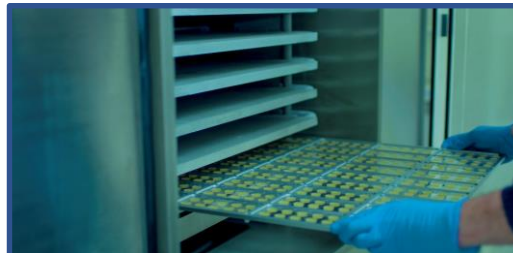


- Specialty pharmaceutical company with expertise in drug delivery systems
- Developed a proprietary sublingual wafer delivery, WaferiX
- Fully integrated business
  - ✓ Drug discovery > Clinical studies > Regulatory > Manufacturing > Sales
  - ✓ Competitive advantages through lower cost of sales, better operating efficiencies & quality control, speed to market & IP protection
- Business strategy
  - ✓ Leverage iX's sublingual wafer technology, WaferiX to better deliver pharmaceutical compounds to address unmet medical needs
  - ✓ Commercialise, either on our own or in partnership with third parties

# Our Facility in Croydon, Victoria Australia



- Modern facility with state of the art equipment; land area 12,000m<sup>2</sup>, build up 3,006m<sup>2</sup>
- Manufacturing facility, iX Syrx Pty Ltd is TGA approved and cGMP compliant



# Corporate Structure



- SGX code: SGX:42C
- Incorporated: January 2008
- Listed: July 2015
- Shares issued: 648.9M
- Share price: \$0.22<sup>1</sup>
- Market capitalisation: S\$143M<sup>1</sup>
- Major shareholders:
  - 1) Eddy Lee - 28.1%
  - 2) Anson Properties - 9.6%
  - 3) Narulla & Associates - 7.0%

<sup>1</sup> As of 29 Jan 2020



# WAFERIX TECHNOLOGY

# WaferiX, iX's Drug Delivery Technology



- WaferiX is a novel, patented, non-invasive and fast-dissolving sublingual wafer that delivers active compounds safely via the oral mucous membrane located under the tongue
- Proven and validated technology – Australian TGA approval received for Wafesil



Intravenous

- ✓ Fastest way to get drug into the system
- ✗ Invasive / Expensive
- ✗ Hospital setting



Oral

- ✓ Convenient / Inexpensive
- ✗ Low bioavailability
- ✗ Variability



Sublingual

- ✓ Disintegrates within 1 minute
- ✓ Rapid absorption; faster therapeutic action and predictable effect
- ✓ Increased bioavailability of actives
- ✓ Convenient and easy to use

# WaferiX Sublingual Wafer



LumeniX glutathione wafer vs glutathione ODT in the market



WaferiX	Oral Dispersible Tablet
Patented technology, fast disintegration	Generic, slower disintegration
Release of actives – instant & complete	Release of actives – slower & incomplete

# WaferiX, Sublingual Wafer Technology



- Patented sublingual wafer formulation
- Proprietary freeze-drying manufacturing process
- WaferiX enables rapid disintegration, instant release of active for immediate sublingual absorption:
  - ✓ highly porous microstructure
  - ✓ homogeneous dispersal of active ingredient(s)
  - ✓ amorphosity of API retained
  - ✓ non-ionic matrix
- Increased bioavailability of actives

## Oral v Sublingual Absolute Bioavailability

Route of Administration	Ketamine <sup>1</sup>	Buprenorphine <sup>2</sup>	Fentanyl <sup>3</sup>
Oral	10-15%	10-15%	30-35%
WaferiX Sublingual	29%	45%	79%

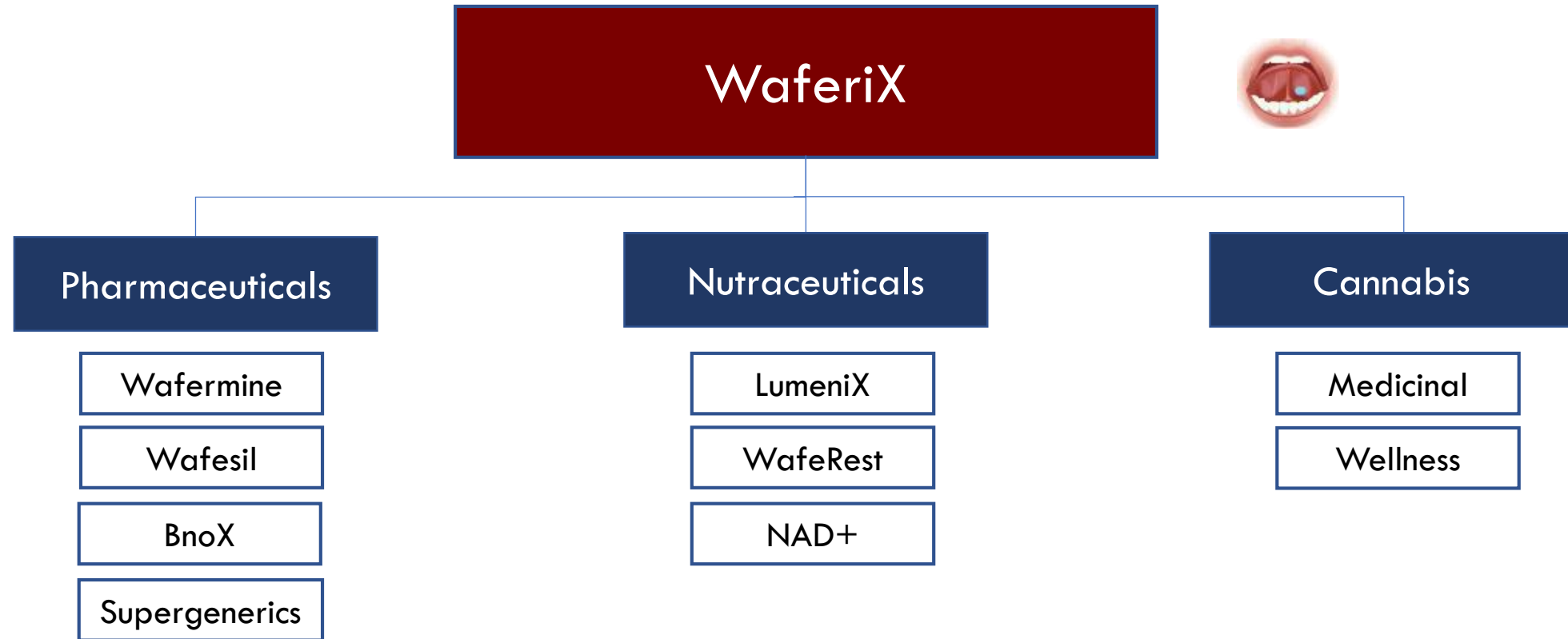
- Ideal for prolonging drug life cycle:
  - ✓ Off-patent drugs (as Supergenerics) ✓ New superior products at lower risk and cost

1. The absolute bioavailability of racemic ketamine from a novel sublingual formulation, British Journal of Clinical Pharmacology, 2013  
2. The Pharmacokinetics and Local Tolerability of a Novel Sublingual Formulation of Buprenorphine, Oxford Journal on Pain Medicine, 2017  
3. A Phase I Pharmacokinetic and Bioavailability Study of a Sublingual Fentanyl Wafer in Healthy Volunteers, Anesthesia and Analgesia, 2012



# PRODUCTS PIPELINE

# WaferiX Products



Competitive advantages of sublingual wafer;  
✓ fast disintegration ✓ rapid onset of therapeutic action ✓ easy to use

# Pharmaceuticals Pipeline



PRODUCT/PROJECTS	PRECLINICAL	PHASE I	PHASE II	PHASE III	REGISTRATION
Wafesil	Male Erectile Dysfunction				AUS TGA
Silcap	Male Erectile Dysfunction				AUS TGA
Wafermine	Acute Moderate to Severe Pain				
BnoX	Acute Moderate to Severe Pain				
Xativa	Anxiety/ Tremor				

# Supergenerics Pipeline



PRODUCT	CLASS	PRECLINICAL	PK STUDY	BE STUDY	REGISTRATION
OTC*					
<b>Loratadine</b>	Anti-histamine	Allergy			
<b>Diclofenac</b>	NSAID	Anti-inflammatory			
<b>Naloxone</b>	Opioid Antagonist	Opioid Reversal			
SCHEDULE 4*					
<b>Midazolam</b>	Benzodiazepine	Sedation			
<b>Sumatriptan/Eletriptan</b>	5-HT antagonist	Migraine			
<b>Tadalafil</b>	PDE-5 Inhibitor	Male Erectile Dysfunction			

\* In Australia

# Wafermine, Sublingual Ketamine Wafer



- Sublingual ketamine wafer for the treatment of pain and depression
  - 1) Acute pain market size US\$7 billion<sup>1</sup>
  - 2) Depression market size US\$13 billion<sup>2</sup>
- Developed under IND (US FDA) for acute moderate to severe pain
  - ✓ Potent non-opioid painkiller, safer than opioids (no respiratory depression)
  - ✓ Can be used as a substitute or adjunct to opioids
- Phase 2 development successfully completed
- End of Phase 2 meeting with US FDA completed, received written outcome in Dec 2019
  - ✓ FDA accepted iX proposed Phase 3 clinical protocol designs
- Strategy is to partner 3<sup>rd</sup> party for development of Phase 3 & product commercialisation



<sup>1</sup>Source: Decision Resources, Pain Management, Acute Pain, October 2014,  
<sup>2</sup>IMS Health, Lundbeck Annual Report 2017

# Wafesil, Sublingual Sildenafil Wafer



How is Wafesil different?

## Wafesil Benefits

- 1) Avoids need to swallow tablets in patients who cannot or prefer not to
- 2) Enhanced pharmacokinetics - potential for faster onset of action & mitigation of food effect
- 3) High level of end-user preference
- 4) Protection from counterfeiting
- 5) Halal, gluten free

Wafesil has received marketing approval in Australia  
It is available in two dose strengths; 25mg & 50mg  
& two different pack sizes; 4 and 8 wafers.





# ENTITY HEALTH

# ēntity, Next Generation Nutraceuticals



It's no surprise many people feel that supplements don't work for them when most are simply vitamins designed to replenish general nutritional deficiencies

We believe Entity delivers more than nutrition, it enhances quality of life

- Entity products:
  - ✓ Are condition specific
  - ✓ Have optimised delivery
  - ✓ Achieve perceptible change



# Nutraceuticals



14 listed products with the Australian Register of Therapeutic Goods (ARTG) ...

# Growth Priorities



- Continue to focus on the Australian market
  - ✓ 215 stockists in Australia to-date including;
    - ◇ pharmacies
    - ◇ health food stores across Melbourne and Sydney
  
- Access China market through cross border e-commerce platforms
  - ✓ Track record established in Australia
  - ✓ Tmall – largest CBEC platform in China for established global brands
  - ✓ JD.com – second largest CBEC platform



# CANNABIS

# Cannabis Market Size



## Global

- Market size in 2018 estimated at US\$13.8 billion; projected to reach **US\$66.3b<sup>1</sup>** by the end of 2025 expanding at a CAGR of 23.9% between 2018-2025

## USA /Canada

- US market size in 2018 estimated at US\$1.9 billion; projected to grow at **CAGR 49%** to **US\$20b<sup>2</sup>** between 2018 & 2024
- Canada market size in 2018 estimated at US\$569 million; projected to grow at **CAGR 44%** to **US\$5.2b<sup>2</sup>** between 2018 and 2024
- More than US\$10 billion invested into the North American marijuana industry in 2018, twice the total amount invested in the previous three years, estimated increase to US\$16 billion in 2019<sup>3</sup>

## Australia

- Total estimated cannabis market value projected to reach **US\$2.1b<sup>4</sup>** by 2028

### Sources

1. Grand View Research, Inc, 2. BD Analytics and ArcView Market Research, 3. Healtheuropa.eu, 4.Prohibition Partners

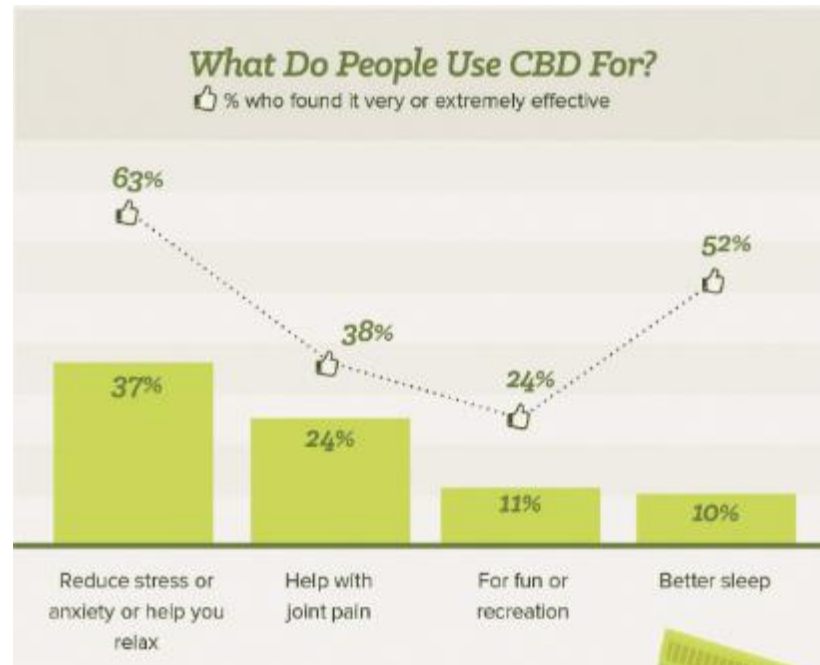
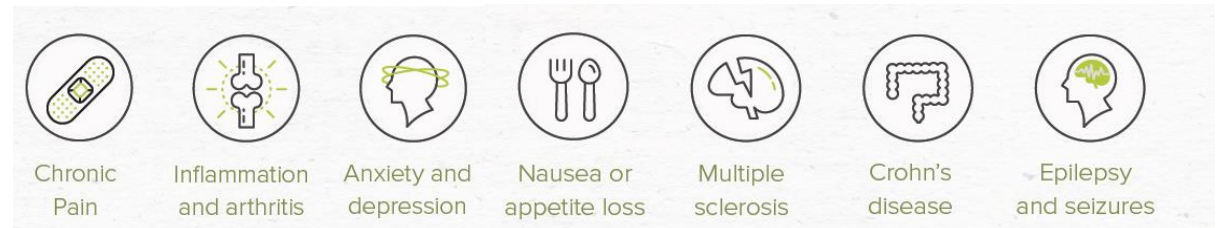
# Cannabis Market Trends



## Cannabinoid preference

- Cannabis plant has 2 major component cannabinoids: THC (psychoactive) & CBD (non-intoxicating)
- Cannabis use previously driven by THC in recreational products & medication for epilepsy & management of cancer symptoms
- CBD use is now escalating rapidly:
  - ✓ Non-intoxicating, won't get high
  - ✓ Therapeutic properties increasingly supported by clinical research
  - ✓ Anecdotal evidence of therapy in a large range of conditions

## Indications for use



Source: consumer reports survey of 4000 Americans

# Cannabis Delivery Formats



Administration	Disadvantages
Smoking / Vaporiser	<ul style="list-style-type: none"> <li>➤ Variable concentration</li> <li>➤ Lack of production controls</li> <li>➤ High potential of adverse effects &amp; 3<sup>rd</sup> party exposure</li> <li>➤ Lack of safety &amp; efficacy data, and no medical use history</li> </ul>
Oral preparations	<ul style="list-style-type: none"> <li>➤ Slow/delayed onset of effect, which is dangerous for THC</li> <li>➤ Poor bioavailability, significant first-pass liver metabolism</li> <li>➤ Variable &amp; inconsistent dosing</li> <li>➤ Not optimised for sublingual administration</li> </ul>

# The Case for Sublingual Delivery

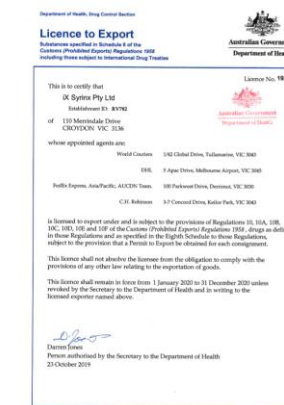


- Sublingual delivery of cannabis is fast becoming the most preferred method of consuming cannabis
- In the US, where the retail markets for cannabis products are well developed, the delivery of choice is sublingual via film
- Why use sublingual dosing?
  - ✓ **Immediate relief** – no waiting for digestive tract absorption
  - ✓ **No negative health effects** – better than smoking or vaporizing
  - ✓ **Accuracy** – nothing lost in extraction so you can dose more accurately than tinctures, smoking & eating
  - ✓ **Safety** – safer & more reliable than edibles, smoking and vaping
  - ✓ **Cost saving** – patients use less, more cost effective solution
  - ✓ **Discreet** – less obvious, better user experience





- TGA GMP  
Manufacturing License





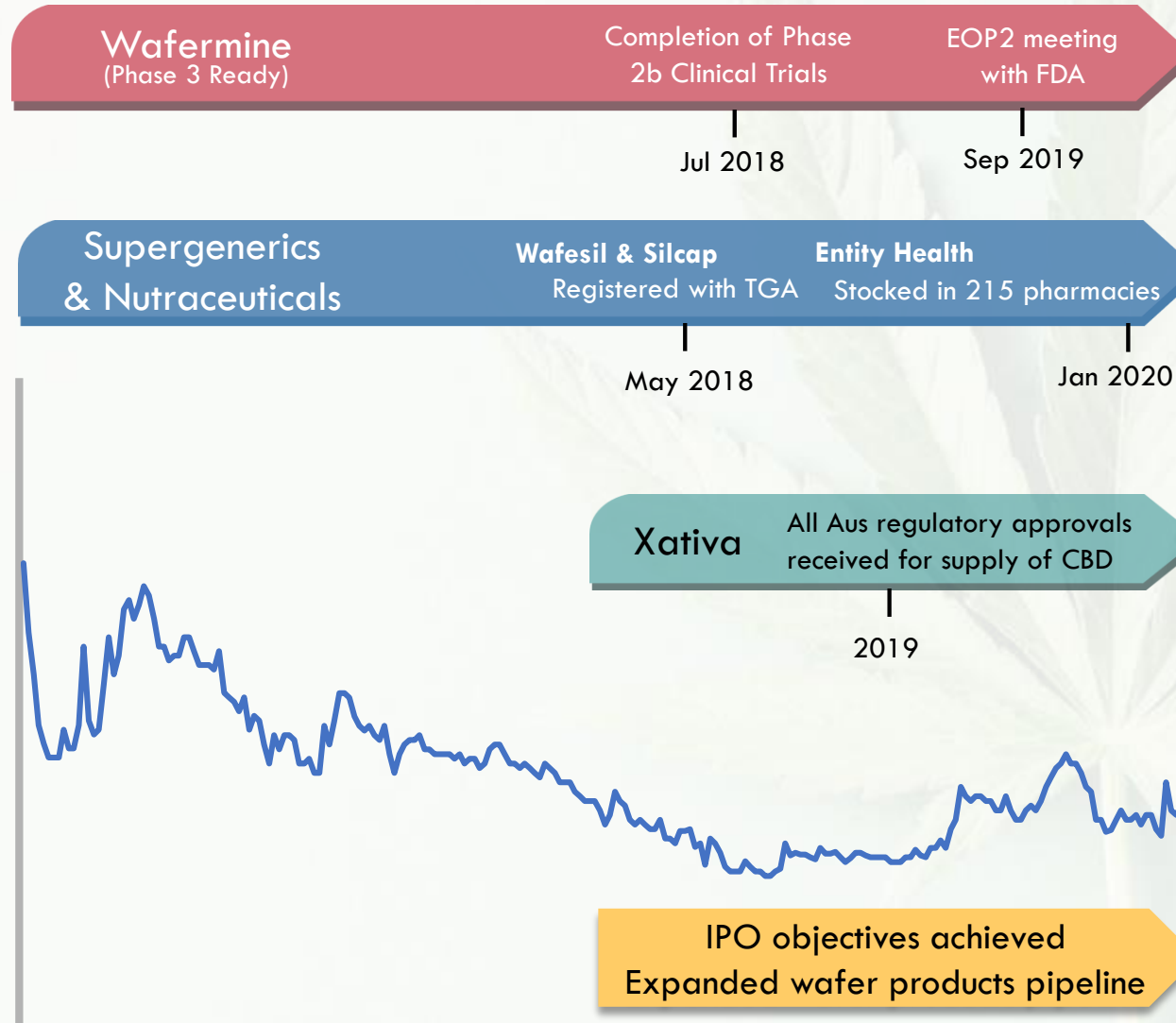
# SUMMARY

2020



## Milestones

## 3 Growth Engines





Thank You