

## ASX Release

# Anatara Investor Presentation

BRISBANE, 13th October 2016: Anatara Lifesciences (ASX:ANR) is pleased to release its latest institutional roadshow presentation and market update that will be delivered to investors over the next two weeks by CEO & Chairman, Dr Mel Bridges and Co-Founder and Chief Scientific Officer, Dr Tracey Mynott.

Presentation highlights include:

- Data on the growing need for a safe and effective alternative to the use of antibiotics in the production of livestock animals and in humans, in line with the United Nations' statement in September 2016 that drug resistance is "the greatest and most urgent global risk"
- The clear path to launch for Detach™, Anatara's natural, non-antibiotic therapeutic to prevent gastrointestinal diseases in pigs, following the Company's recent application to register the product for marketing with the Australian Pesticides and Veterinary Medicines Authority
- An overview of the competitive landscape for other therapeutics used to treat gastrointestinal disease in pigs
- A status update on the Company's efforts to move its technology from pigs into humans, along with the commercial rationale for doing so.

A copy of the presentation follows.

### For more information please contact:

| Investor inquiries  | Media inquiries  |
|---|--|
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### About Anatara Lifesciences

Anatara Lifesciences is developing therapeutics for gastrointestinal diseases in production animals and humans. Its lead product Detach™ is a natural plant based product that will help address global concerns around the overuse of antibiotics in production animals that is contributing to the rise of so-called "super bugs" that make infectious diseases harder to treat. The Anatara team has a strong track record in biological science as well as building and growing international biotech companies.





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# Natural Alternative to Antibiotics

October 2016



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# Key Financial Details

**ASX Code**

**ANR**

Share Price<sup>1</sup>

\$1.19

Market Cap

\$58.7 million

Ordinary Shares<sup>2</sup>

49,288,246

Current Cash<sup>3</sup>

\$13.8 million

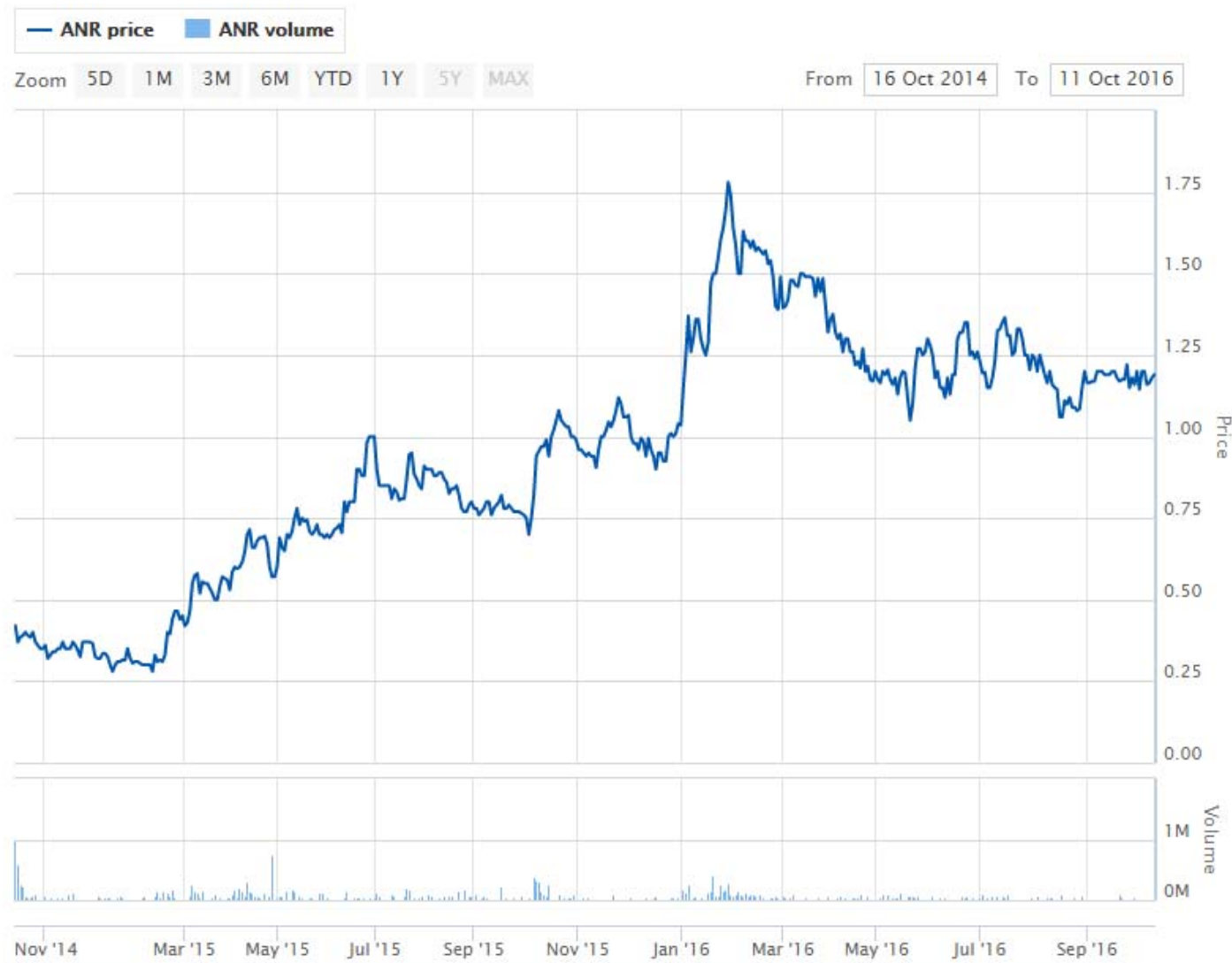
1. As at 12 October 2016

2. 13,036,095 shares held by directors, other related parties, and persons who have received shares from these parties are subject to escrow until 17<sup>th</sup> October 2016.

3. Appendix 4E - 30 June 2016



# ANR Share Price Chart





# *Oral therapeutics for gastrointestinal disease in livestock and humans*

## Detach™

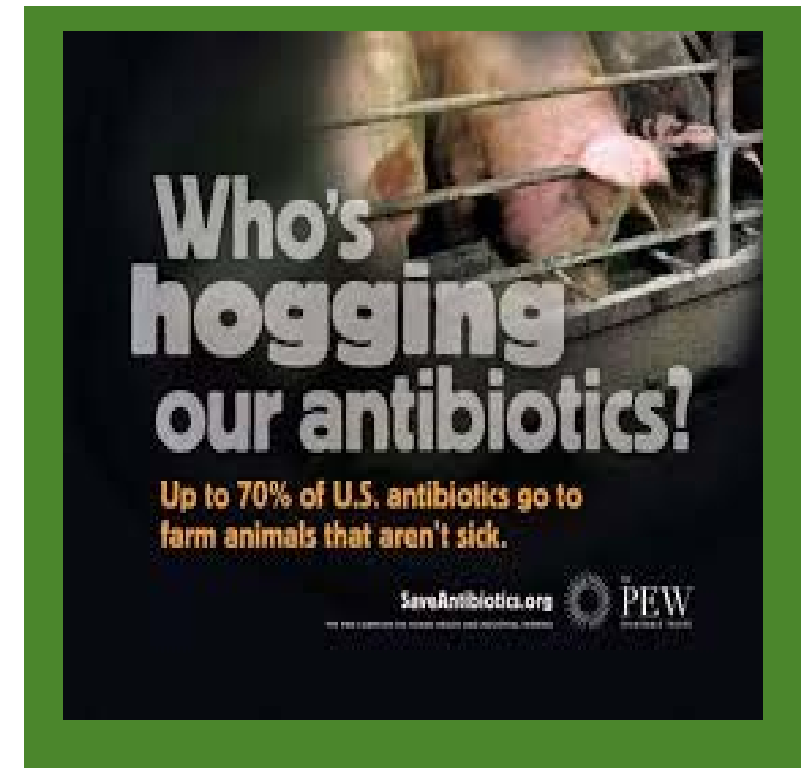
- Natural, non-antibiotic therapeutic that prevents and treats gastrointestinal diseases including diarrhoea
- Meets the need to reduce antibiotics in animal production
- Unlike antibiotics, Detach™ will not contribute to antimicrobial resistance



# Market Need – Anti-microbial resistance

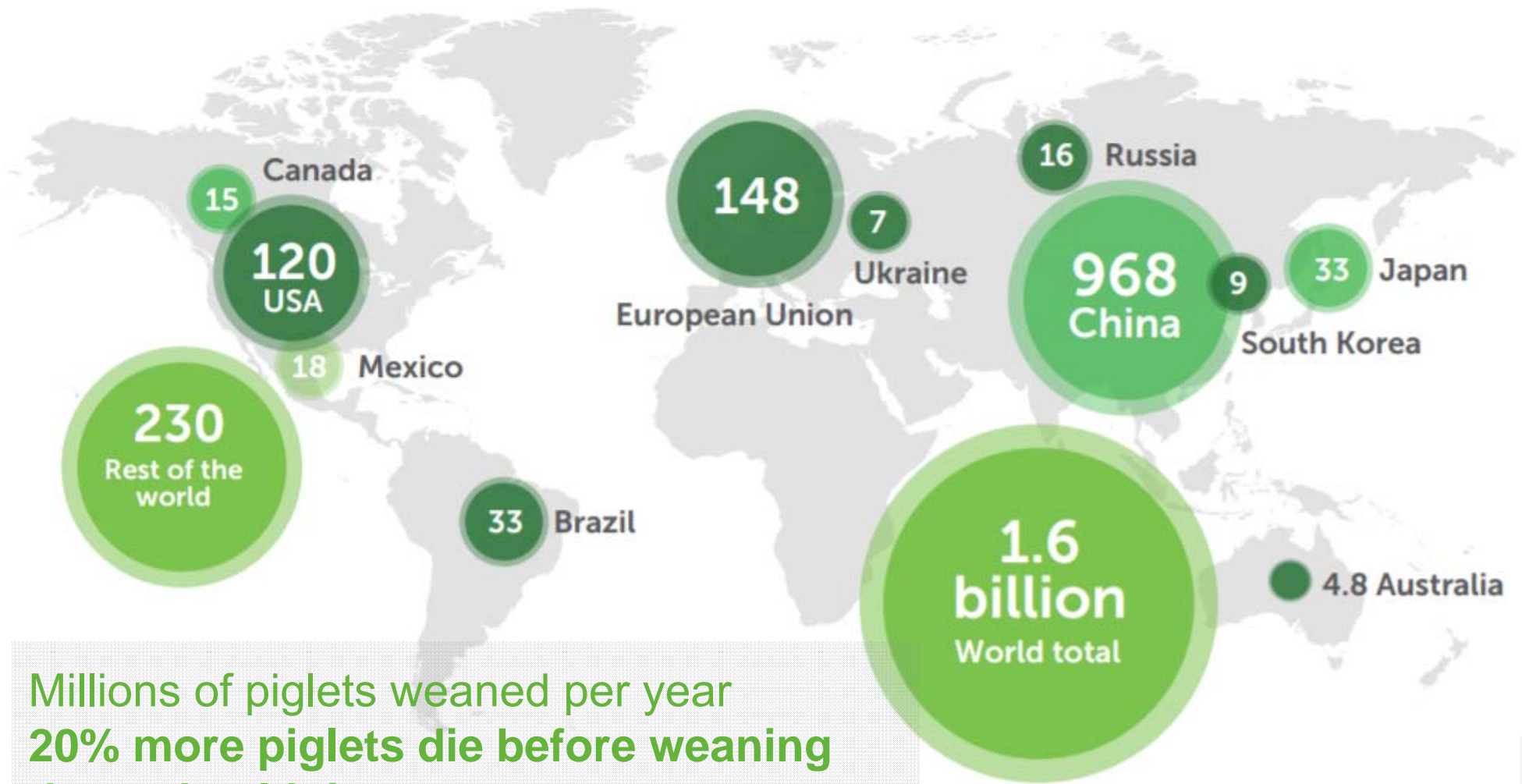
*‘the greatest and most urgent global risk’*

- United Nations convened a high level meeting on anti-microbial resistance on 21 Sept 2016, calling AMR “**the greatest and most urgent risk**”
- Around 700,000 people die per year from antibiotic resistant “superbugs”  
*(Wellcome Trust)*
- Wide acknowledgement that antibiotic resistance is driven by antibiotic overuse — in man and animals



# Lead indication – pigs

Diarrhoea affects hundreds of millions of piglets born each year



Millions of piglets weaned per year  
**20% more piglets die before weaning  
due to health issues**





# Market Opportunity is clear

- Detach™ addresses a major need
- Global animal antibiotic market valued at ~ \$4.63 billion in 2014<sup>1</sup>. Production animals 70%. Pigs lead by market share of 25%.
- Pork is #1 consumed meat in the world
- Global demand for meat is rising. More than 85% more meat needed by 2030<sup>2</sup>.
- Detach™ can be developed for chickens, calves and humans



# Market Drivers

- World authorities are banning growth promoting antibiotics and restricting prophylactic antibiotics in animal production
- Consumers want their meat to be safe
- Retailers are demanding antibiotic free produce
- McDonald's, Subway and hundreds of other global food companies have put plans in place to supply antibiotic-free meat to their customers.
- Pork producers need effective alternatives to antibiotics



# Anatara – A solution

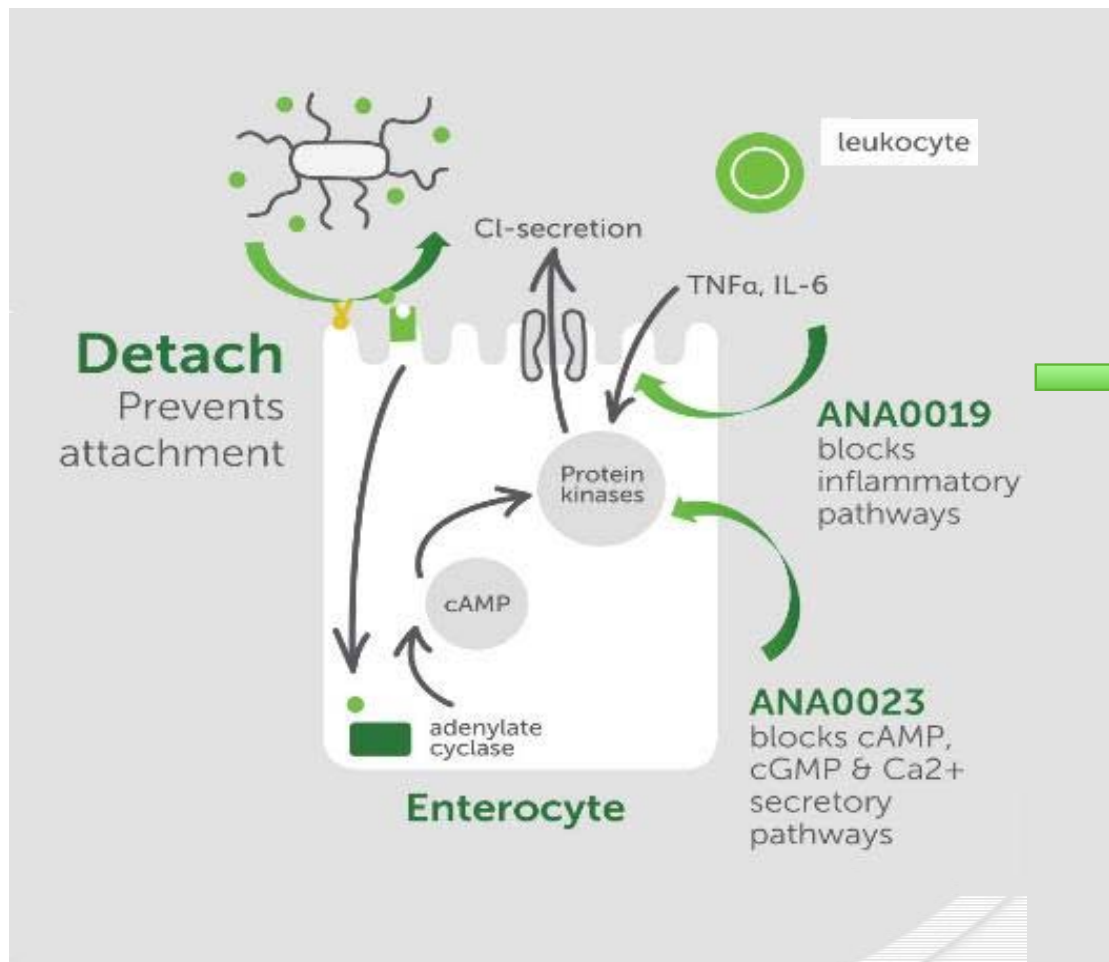
- Detach™ is an orally administered non-antibiotic anti-infective
- Proven efficacy – evidence-based therapeutic claims
- Proven safety - active ingredient is a natural plant based product
- Broad acting against a range of causes of diarrhoea
- Stable - does not require refrigeration
- Unlike antibiotics, Detach™ will not lead to antimicrobial resistance
- Proven economic benefits for farmers
- Strong Intellectual Property portfolio
- Peer-reviewed publications in high impact academic journals



# Detach™ Mode of action

Detach™ does not target the pathogen

Detach™ acts on the underlying cause of diarrhoea



Anti-inflammatory opportunities

1. Chandler and Mynott. 1998. *Gut* 43:196-202.
2. Mynott, et al., *Gut* 38:28-32.
3. Mynott, et al. 1997. *Gastroenterol.* 113:175-184.
4. Mynott et al. 1999. *J. Immunol.* 163:2568-2575



# Detach™

## Poised for swift market entry

- Registration application submitted to the APVMA
- Launch planned in Australia for 2017
- A clear path to market
  - *Proven efficacy (therapeutic claims)*
  - *Proven safety - active ingredient is GRAS (generally recognised as safe)*
  - *Manufacturing complete at commercial scale and global supply confirmed*
- Introduction of Detach™ is supported by industry, government, retailer & consumer demand
- Commercially validated



Current 50 kg scale  
(≈500,000 doses)



1,000 kg capacity  
(≈8,500,000 doses)



# Commercialisation Strategy

## Livestock

- **Market** - Anantara will market Detach™ in Australia and NZ directly to pork producers – a heavily consolidated industry
- **Supply** - Detach™ will be supplied in Australia via pre-existing distribution channels
- **Partner** - Co-development and commercialisation partners for Detach™ globally and other livestock species. Eg. Zoetis option to license agreement
- **Expansion** – Seek partnerships for humans



# Exclusive Option to license Detach™ for worldwide commercialisation with Zoetis

- Zoetis (zō-EH-tis) are the **#1 global animal health company**
- **~\$5 billion** annual revenue, **~\$26 billion** market cap

## Option:

- Aggressive program for evaluation of Detach™ in multiple livestock species in progress
- Zoetis are funding cost of validation trials
- Upfront payment received
- Subsequent cash payments scheduled
- Further strengthened Anantara Balance Sheet
- IP remains the sole property of Anantara
- Anantara retains rights to AUS and NZ
- Validation of Detach™ technology

The Zoetis logo is displayed in a bold, orange, sans-serif font. The letters are slightly italicized, giving it a dynamic feel. The 'Z' is particularly prominent with a thick stroke.

# Competition and Limitations

| Description   | Example   | Limitations  |
|---------------|---|--|
| Antibiotics   | Trimethoprim/sulfadiazine,<br>Neomycin, Lincospectin<br>(\$0.31 to \$3.50/pig)      | Contributes to AMR/residues<br>Not effective against viruses   |
| Antimicrobial | Zinc Oxide<br>(widely used although not<br>approved in Australia)<br>(\$0.34 / pig) | Antimicrobial resistance<br>Environmental issues/residues<br>Reduced palatability<br>Quality control issues<br>Not approved in all countries |
| Vaccines      | Autogenous<br>Multivalent<br>Pathogen specific<br>(up to \$3.00 per pig)            | Pathogen specific<br>Prevention only   |
| Non-specific  | Organic acids<br>Essential oils<br>Probiotics                                       | Variable efficacy  |





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## Human Applications

*There are 4 billion episodes of diarrhoea in the world annually.*

*Diarrhoea is the second cause of death in children under 5 years, and the leading cause of malnutrition.*



# Anatara technology – for humans

- Several different product opportunities based on modified forms of Bromelain-Rx
- These products could be used to treat several human gastrointestinal conditions, such as:
  - Diarrhoea
  - Inflammatory bowel disease and
  - Irritable bowel syndrome
- No product available that prevents all causes of GI diseases
- Diversity of diarrhoea poses a difficulty for drug developers





# Human gastro related disorders/disease



## Traveller's diarrhoea

**50 million**  
travellers at risk per year.  
Rising to 100 million by 2020.



TD is a threat to military efficiency  
and preventative treatment is a  
priority for the US Army



## Developing countries

**#2** cause of death in under 5's  
(1.3 million kids per year.)



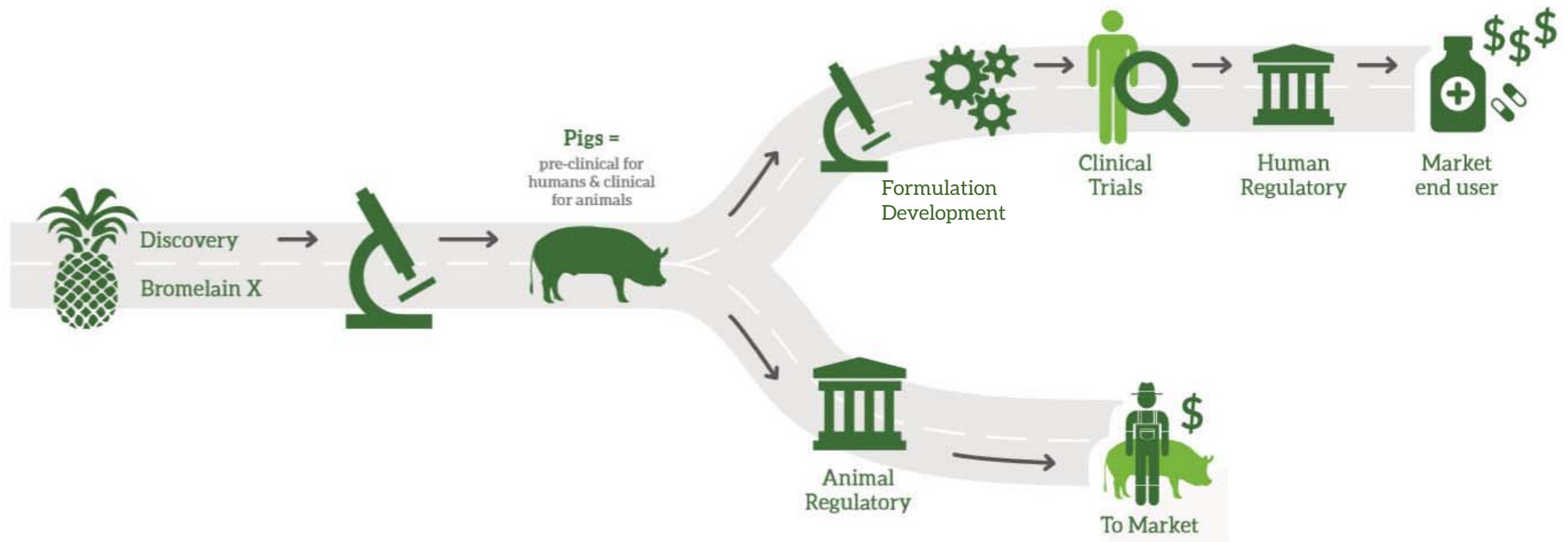
## United States of America



~ 211-375m episodes of diarrhoea p.a.  
116m people use anti-diarrhoea medication (31%).



# Detach™ - From pigs to people



Detach™  
- From Pigs  
to People

- Same mechanism of action for treatment of disease in pigs and humans
- Pre-clinical program for animals complete therefore development for humans de-risked
- Clinic ready (CMC, Toxicology, Pharmacology well developed)
- Ready to Partner/Develop



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# Detach™ for Humans

## Status

- Mode of action clearly understood, based on decades of research
- Pre-clinical efficacy database is very strong due to leverage of Detach™ data from pig studies
- Proof of concept in several animal models
- Confirmed efficacy in rabbit models with human diarrhoea pathogens
- Proof of concept in mouse model of inflammatory bowel disease
- Margin of safety studies (1x, 3x and 5x dose) in piglets completed (TAS study)
- Human Safety studies (Phase I) in healthy volunteers completed
  - 28 day treatment was very well tolerated



# Human Development Program underway

## La Trobe University, Melbourne collaboration

- Advances Anantara's pipeline of products to treat gastrointestinal and inflammatory diseases in humans
- Program includes the production, validation and pre-clinical evaluation of specific components isolated from the active ingredient in Detach™
- New opportunities and product extensions
- Partnering discussions initiated





# Key Milestones

|   | Status    |
|---|-----------|
| USA Fee Waiver Granted  | complete  |
| Pork CRC Partnership  | complete  |
| Meet with FDA/CVM and EU regulators                                     | complete  |
| New patents filed   | complete  |
| Australian Field Trials   | complete  |
| 1 <sup>st</sup> Partnering Deal   | complete  |
| Animal Safety Trials (TAS study)  | complete  |
| Submit Dossier to APVMA   | complete  |
| Human Development program starts<br>- La Trobe university collaboration | initiated |
| Appoint Australian/NZ Distributors                                      | 2017      |
| APVMA Approval and sales commence                                       | 2017      |
| Human Partnering Deal   | 2017      |





# Anatara Investment Overview

- Experienced Board and management team with proven track records
- Seasoned Operational Team:
  - Regulatory – *Experienced Australia, EU and USA team*
  - Manufacturing - *TGA and APVMA licensed GMP facility. FDA audited.*
  - Clinical Trials – *Experienced through to registration*
  - Commercial – *Experienced in Sales & Marketing*
- Focus: Developing natural, plant-based products proven to enhance gastrointestinal health
- Lead product, Detach™ to control diarrhoea in piglets has a clear route to market:
  - Commercially validated and proven efficacy
  - Development strategy de-risked and revenues within 1 year
- Well funded – sufficient to launch Detach™ in AU, EU and USA
- Product pipeline – animal product leads to human product development for partnering / licensing
- Products have broad clinical applications and importantly, scientific and clinical evidence of efficacy, health benefits and safety.





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# Thank you

*“With the world’s meat production needs set to rise 100% by 2050, it is important we act now to develop non-antibiotic treatment options.”*

Dr Mel Bridges, Chairman – Anatara Lifesciences



# Questions

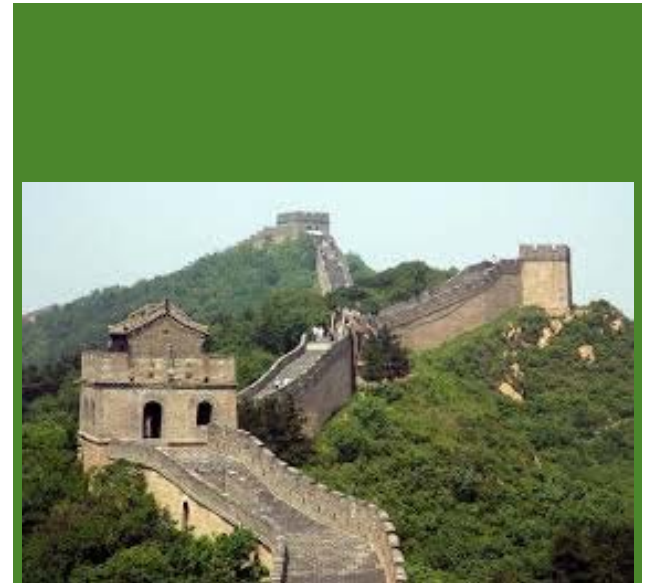
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# Intellectual Property

- PCT application filed (August 2015)
- Second PCT application filed (August 2016)
- Solid patent strategy in place for further patents to be filed in major territories
- Claims cover the Detach™ formulation, as well as use of the active ingredient and composition of matter for the active components within Bromelain-Rx
- Bromelain-Rx is not the same as common bromelain
- Detach™ formulation has superior efficacy to bromelain or bromelain-Rx alone



IP wall of China



# Detach™ Field Trial Summary

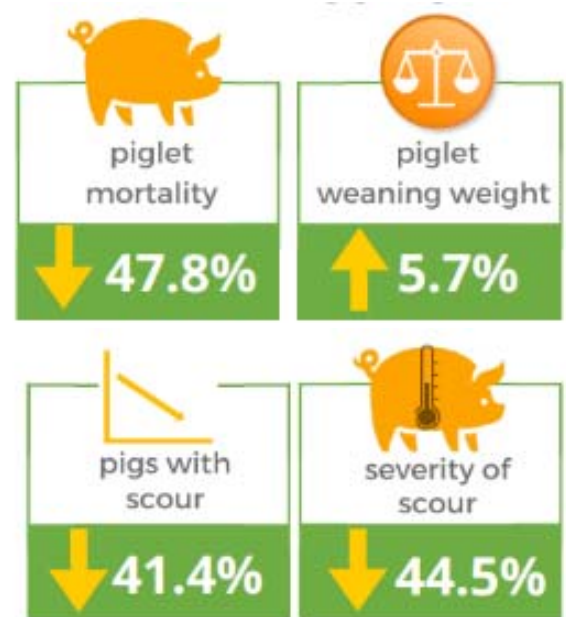
## Previous Trials

- 20 positive field trials on commercial farms
- Detach™ safe and effective in several thousand piglets

## Registration Trials

- Successful trial in Spain (ANR 12-001)
- Successful trial in Northern Victoria (ANR 14-001)
- Successful trial in South East Queensland (ANR 15-001)
- Successful results in different age groups, in different geographical locations and under different clinical scenarios (mild and severe conditions)
- Final trial – farm selected and in advanced planning (Back up sites under evaluation)

### DETACH™ FIELD TRIALS





# Target Animal Safety Study

- GLP Target Animal Safety (TAS) Study in 2 day old piglets
- Study provides detailed safety data for piglets and humans
- 40 piglets (n=10 per group, 4M:4F) administered 0x (placebo), 1 x, 3x and 5x the recommended dose every 3-4 days for three weeks
- Detach™ proven to be very safe at doses and frequency that far exceed the recommended regimen
- Safety assessed by clinical observations, body weight gain, tissue weights, tissue histopathology, haematology, serum chemistry and urine analysis (VICH GL43)

