



# Annual General Meeting

12 November 2018



**ANATARA**  
LIFESCIENCES

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# Key Investor Message

Anatara Lifesciences (ASX:ANR) is developing and commercialising innovative, evidence-based products for gastrointestinal health where there is significant unmet need.



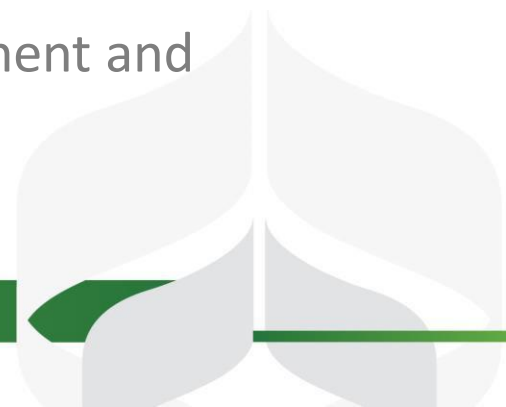
# Company Highlights

- Negotiated an exclusive **global licensing agreement** for the worldwide development, distribution and marketing of Detach with **Zoetis Inc - #1 global animal health company**
  - USD500K remainder of upfront payment received
  - Technical transfer complete
- Detach received regulatory approval from **Australian Pesticides and Veterinary Medicines Authority (APVMA)** for use in piglets
- Growth in Anatará's skill set, with two key appointments with significant **human health experience**:
  - Sue MacLeman and
  - Dr Jane Ryan, to the Board of Directors



# Company Highlights Cont.

- **Human development** program well underway - developing scientifically innovative and commercially attractive products for **gastrointestinal health** in areas of **critical need**
- First product candidate - **Gastrointestinal ReProgramming (GaRP) dietary supplement** is aimed at restoring and maintaining **gut health** - proof of concept studies are well advanced
- Formation of our **Product Development Advisory Board**
  - World-leading scientists and clinicians in gastrointestinal health
- Company well funded with \$7.1m in bank
  - ~\$1,230,000 **R&D tax refund** received for 2016-17 activities
  - **Sufficiently funded** to execute on the development and partnering of our GaRP dietary supplement



# Patient Stories

You will now hear from three patients who are living with IBS or IBD and the impact it has on their lives. They will highlight their most difficult symptoms to manage and their own experiences with the effectiveness of current therapies and management practices.





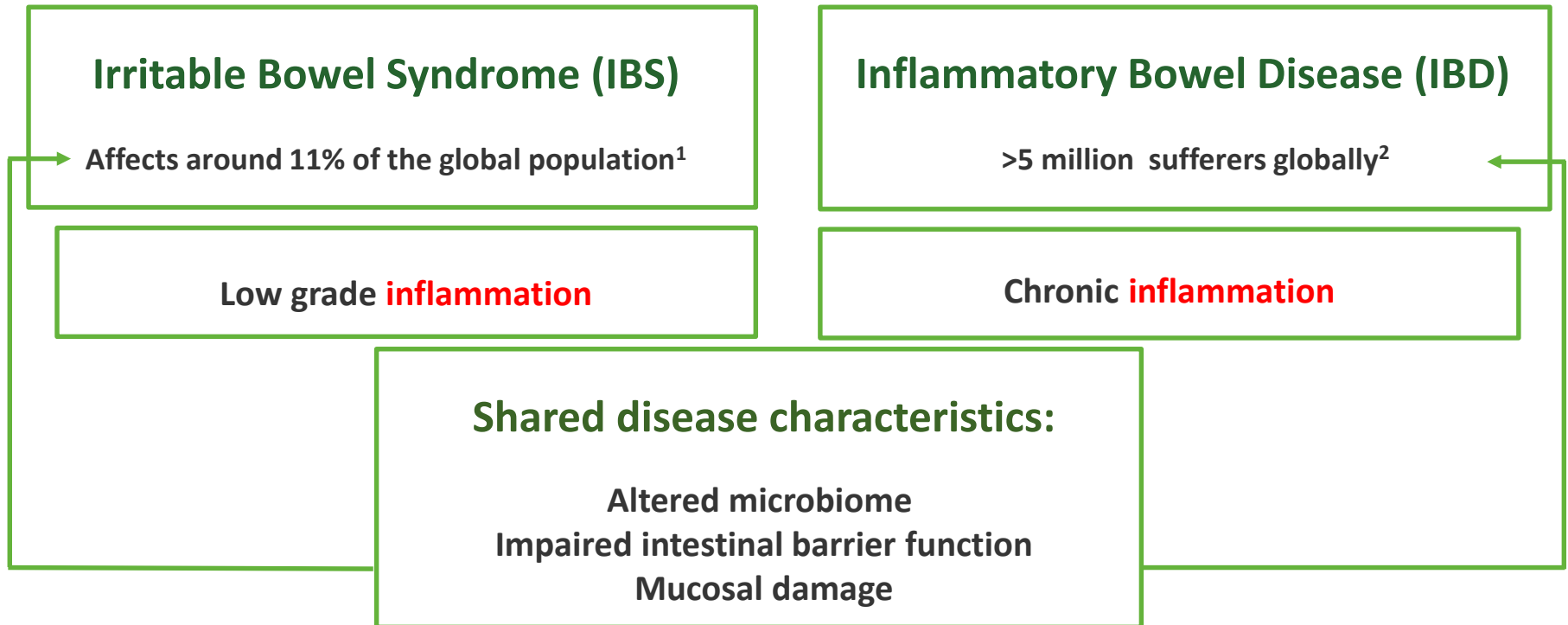
Anatara has designed a novel product aimed at restoring and maintaining gut health:

## **Gastrointestinal ReProgramming (GaRP) Dietary Supplement**

For the Management of  
Gastrointestinal Disorders



# Target Gastrointestinal Disorders



## IBS and IBD are areas of significantly unmet clinical need

Anatara's GaRP aims to:

- Re-establish the homeostasis of the gut microbiome
- Treat the inflammation
- Repair the mucosal damage

**THEREBY** reduce the associated diarrhoea.



# The Microbiome and IBS/IBD

## Healthy gut microbiome

- Supplies energy and nutrients
- Immune system development
- Defence against pathogens



Healthy gut – increased diversity

## IBD/IBS gut microbiome

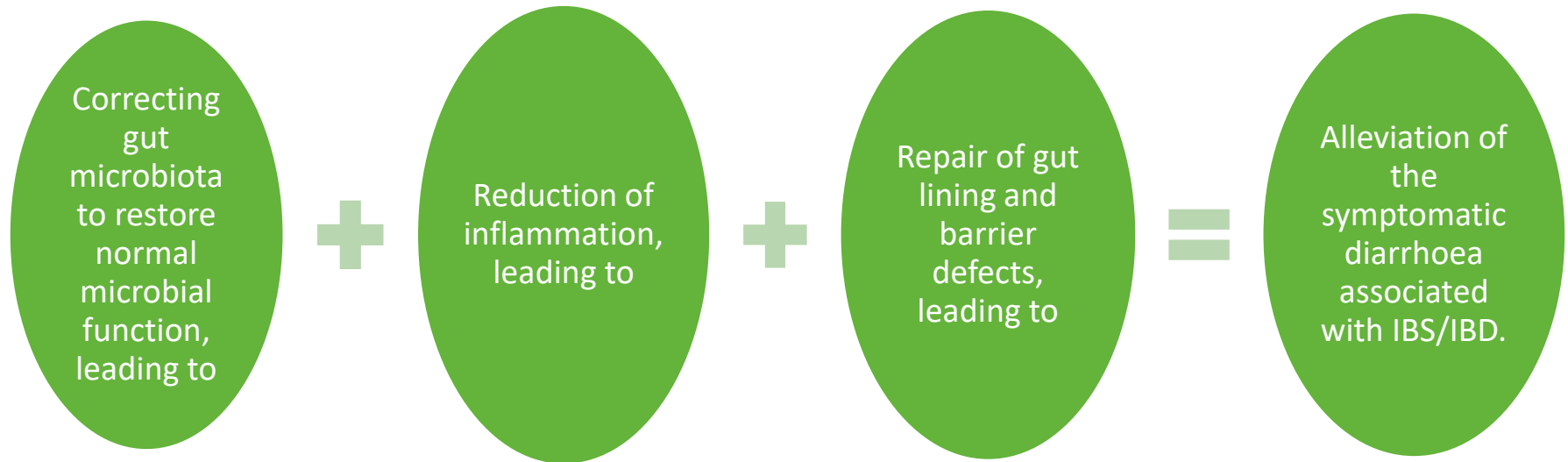
- Less bacteria with anti-inflammatory properties
- More bacteria with pro-inflammatory properties
- Reduction of diversity
- Change in overall bacteria numbers



Unhealthy gut – lack of diversity

# How GaRP works?

GaRP is a microbiome-targeted dietary supplement aimed at:



GaRP will be used as an **adjunct** to existing treatments.



## Dietary Supplements as an adjunct to prescription drugs for the treatment of GI disorders

- ~50% of patients seek additional relief of their symptoms through adjunct therapies
- Increased education and more detailed evaluation of dietary supplements has led to health-care providers working with patients to develop individualised programs which include dietary supplements in the symptom management for GI disorders.



GaRP – built on strong  
scientific foundations



# About bromelain



## Generally Recognised as Safe (GRAS)

Bromelain is allowed in food as a food additive and it has been affirmed as Generally Recognised as safe (GRAS) allowing it to be **considered as a food**.



## Unlimited Acceptable Daily Intake (ADI)

Bromelain has been used for decades in as an anti-inflammatory and anti-cancer complementary medicine in the USA and Europe. This has established it to be safe with an **unlimited Acceptable Daily Intake**



## But formal clinical data has been lacking

A lot of anecdotal evidence regarding its clinical efficacy but the bromelain is poorly characterised and therefore has variable activity resulting in **no definitive clinical data**



## Until now...

Anatara has developed a **bromelain fingerprint** where different biological activities are associated with specific parts of the bromelain fingerprint

This will be utilised in our human therapeutic programs





Dual targeted product  
combining bromelain and  
other GRAS components\*

**Ileum targeted components**

- prevent attachment of pro-inflammatory bacteria
- restore gut microbiota
- reduce inflammation

Ileum

**Colon targeted components**

- restore gut microbiota
- reduce inflammation
- mucosa regeneration
- restore gut integrity
- reduce diarrhoea

Colon





# GaRP Development Plan

- **Commercial Feasibility-** confirming the clinical and market need for a multi-functional dietary supplement that could act as an adjunct to current IBD and IBS medications.
- **Proof of concept studies** are well advanced to demonstrate that GaRP can:
  - Remove bacteria with pro-inflammatory properties
  - Reduce inflammation by reducing the release of proinflammatory cytokines
  - Regenerate the integrity of the gastrointestinal tract
  - Stimulate mucosal healing
- **Formulation Development** – coated, dual-release preparation
- **Efficacy Testing** – in rodent IBD and IBS disease models followed by testing in pigs (preclinical development in an adult pig model reduces the risk of formulation failure in a human)

# Regulatory advantages of dietary supplements\*

**The advantages of a dietary supplement regulatory strategy are:**

1. Less expensive and less risky pathway to market
2. Rapid market entry
3. Public and health care professionals understand the term 'dietary supplement'
4. Marketing can be aimed at both the public and the professional.

\* Dietary Supplement are foods intended to supplement the normal diet which are concentrated sources of one or more nutrients, like vitamins, proteins, mineral complexes, herb or other botanical, amino acid or enzymes.



# A clear path to commercialisation

	2017 H1	2017 H2	2018 H1	2018 H2	2019 H1	2019 H2	2020 H1	2020 H2
Confirmed GRAS status for components with FDA	✓							
Established collaboration with University of Liverpool (UK)		✓						
Completed product development plan		✓						
Patent Application filed				✓				
Commercial feasibility			✓					
Manufacturing – sourced suppliers		✓						
Proof of concept			→					
Efficacy studies					→			
Partnering discussions			→				→ *	

# Product Development Advisory Board



Professor Peter Gibson



Dr Rebecca Burgell



Dr Jakob Begun



Professor Barry Campbell



Professor Simon Keely

- Advisory Board members are internationally recognised for their expertise in IBS and IBD with experience ranging from preclinical drug development through to translational research and clinical trials.
- The role of the Advisory Board is provide advice on Anantara's research and product development programs in gastrointestinal health.





Thank you



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