

#### **ASX** Release

#### Investor presentation and strategy update

BRISBANE, 18<sup>th</sup> July 2018: Anatara Lifesciences (ASX:ANR) is pleased to release its latest presentation and strategy update that will be delivered to institutional investors this week.

In outlining its future strategy, Anatara has provided an update on its efforts to develop its product pipeline, extending from its core application to control diarrhoea in pigs, to the management of human gastrointestinal disorders such as Irritable Bowel Syndrome and Inflammatory Bowel Disease.

#### The presentation also summarises:

- The exclusive global agreement with Zoetis for the worldwide development, manufacturing, distribution and marketing of Detach in livestock and horses
- Anatara's human gastrointestinal program which has been reviewed and refined, resulting in a strong lead product for restoring and maintaining gut health
- Enhancement of Anatara's Intellectual Property position
- Confirmation that the Company has funding in place to progress the first human product through to anticipated partnering

A copy of the investor presentation follows. A letter to shareholders has also been lodged today which provides further context to Anatara's strategy moving forward.

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#### **About Anatara Lifesciences**

Anatara Lifesciences (ASX: ANR) develops and aims to partner non-antibiotic, oral products for gastrointestinal diseases in animals and humans where there is significant unmet need and large market opportunity. In May 2018, Anatara granted an exclusive licence to the leading global animal health company, Zoetis Inc., for the worldwide development, manufacturing, distribution and marketing of its lead product Detach as a non-antibiotic approach to aid in the control of diarrhoeal disease (known as scour) in livestock and in horses. Anatara is now focused on developing its human product pipeline for gastrointestinal health applications. For more information, please visit www.anataralifesciences.com.





## From animals to humans

July 2018

Dr Jay Hetzel, Chairman Dr Tracie Ramsdale, CEO Dr Tracey Brown, CDO Anatara Lifesciences (ASX:ANR)



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## **Anatara Corporate History**

#### **ASX Listing**

First commercial scale up of Detach manufacture

2014



2015

## Positive Field Trial results

Capital raising

INAD open in USA

Positive FDA and VMD meetings

**Zoetis Option** 

**Expand Management Team** 

Melbourne lab established

Target animal safety (TAS) study complete

Submit Detach dossier to APVMA

2016



Global License with Zoetis for Detach for livestock and horses

2018



Q R S T M N

2017

Positive Health Canada VDD meeting

Initiation of GaRP product development program

FDA confirmation of GRAS for bromelain and its components

FDA 

Human Food Safety





Detach developed

Discovery of active components

Proof of concept laboratory work

Seed Investment



## **Presentation Highlights**

- Signed exclusive global agreement with Zoetis for the worldwide development, manufacturing, distribution and marketing of Detach in livestock and horses
- Human gastrointestinal program reviewed and refined, resulting in strong initial candidate for restoring and maintaining gut health
- Enhanced IP position
- Funding in place to progress the first human product through to anticipated partnering in 2020
- Current cash \$8.8 million.\*

Anatara develops and aims to partner non-antibiotic, oral products for gastrointestinal disease in humans where there is significant unmet need and large market opportunity

\* Appendix 4C - 31 March 2018



### **Animal Health**

- A natural, safe, non-antibiotic product that aids in the control of diarrhea (known as scour) in livestock
- Anatara has signed an exclusive licensing agreement with Zoetis Inc., the leading global animal health company, for the worldwide development, manufacturing, distribution, and marketing of Detach for livestock animals and horses
- Upfront payment of US\$2.5m, aggregate milestone payments of up to US\$6.3m and royalty of 3-4%













# From animals to humans

## **Anatara's Technology**

- Bromelain is a natural product extracted from pineapple stems.
- Based on decades of research by worldclass academic and commercial partners which found that bromelain contains a number of proteases with distinct biological activities, including
  - Anti-attachment
  - Anti-secretory
  - Anti-inflammatory

Potential applications in humans include gastrointestinal (GI) diseases that involve inflammation and/or diarrhea





Anatara molecules are extracted from "stems" of the pineapple plant



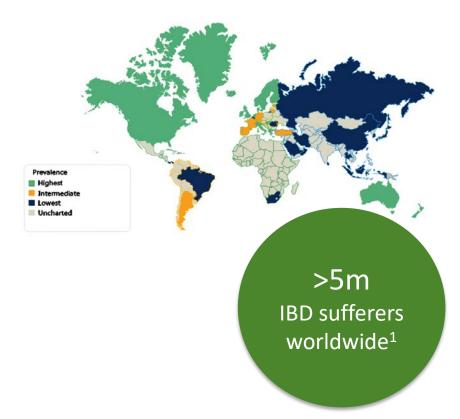
## Human strategy – strategic review

- Potential applications for Anatara's technology exist in
  - childhood diarrhea
  - traveller's diarrhea
  - diarrhea associated with gastrointestinal disorders such as IBD and IBS
- Following a thorough review of each of these opportunities, the IBD/IBS indication was selected on the basis of:
  - Market potential
  - Competitive advantage
  - Quality of supporting data
  - Strength of intellectual property protection
  - Speed to market
- Anatara has elected to develop a novel product aimed at promoting gut health and managing the symptoms associated with gastrointestinal disorders such as IBD and IBS
- Leveraging off large amount of data previously generated



## About Inflammatory Bowel Disease (IBD)

- Two forms: Ulcerative Colitis and Crohn's Disease
- Patients experience abdominal pain and cramping, bloating, blood and mucus in the stool, loss of appetite and persistent diarrhea
- Treatment involves suppressing inflammation with the goal of inducing and maintaining remission
- 30-50% of IBD patients<sup>2</sup> turn to complementary and alternative medicines

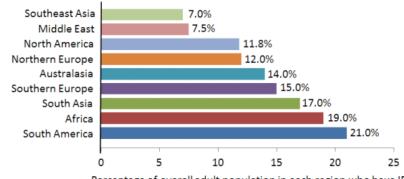


IBD is a global disease with accelerating incidence in newly industrialised countries



## About Irritable Bowel Syndrome (IBS)

- IBS is a functional disorder. Incomplete knowledge of pathology, therefore the approach is symptom management
- Symptoms include abdominal pain, bloating and alternating constipation and diarrhea
- Patients have a poor quality of life and utilise the healthcare system more than other patients
- ~50% of patients<sup>4</sup> turn to dietary supplements and complementary medicines



Percentage of overall adult population in each region who have IBS

25B USD
Gl and Digestive
Health
Nutraceuticals
Market\*

36B USD
by 2021
CAGR 8%\*

Affects around 11% of the global population<sup>3</sup>

The most commonly diagnosed gastrointestinal condition and a significant health care burden

<sup>3</sup>Clinical Gastroenterology and Hepatology 2012: 10, 712-721 <sup>4</sup>World J. Gastroenterol 2014: 346-362



ANATARA LIFESCIENCES

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

Gastrointestinal Reprogramming Product (GaRP)

For the Management of Gastrointestinal Disorders



## Target Gastrointestinal Disorders

Irritable Bowel Syndrome (IBS)

Low grade inflammation

Inflammatory Bowel Disease (IBD)

**Chronic inflammation** 

#### **Shared disease characteristics:**

Altered microbiome
Impaired intestinal barrier function
Mucosal damage

#### 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 diarrhea.



## The Microbiome and IBD/IBS

#### Healthy gut microbiome

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

#### IBD/IBS gut microbiome

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



Healthy gut – increased diversity

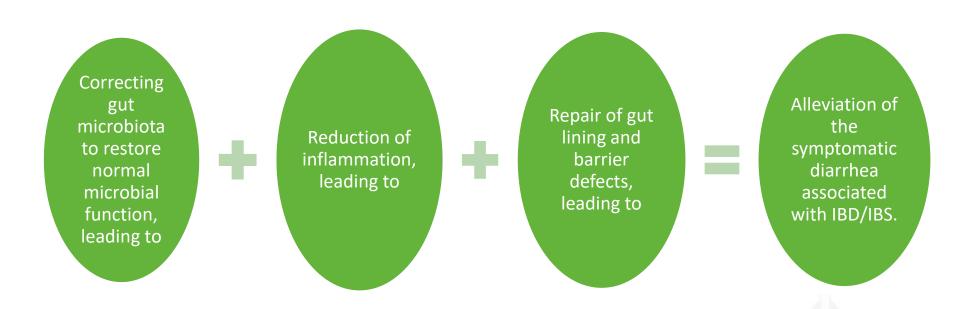


Unhealthy gut – lack of diversity



## How GaRP works?

GaRP is a microbiome-targeted <u>dietary supplement</u> aimed at:



GaRP will be used as an adjunct to existing treatments.



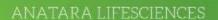


# Dietary Supplements as an adjunct to prescription drugs for the treatment of GI disorders

- GI disorders affect a significant proportion of the population.
- ~50% of patients seek additional relief of their symptoms through adjunct therapies
- Increased education and more detailed evaluation of dietary supplements has led to healthcare 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

#### **Colon targeted components**

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

## GaRP Development Plan- next steps

- 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
  - Reduce serotonin-induced diarrhea (important for IBS)
  - Regenerate the integrity of the gastrointestinal tract
  - Stimulate mucosal healing
- Formulation Development coated, dual-release preparation
- Dose Optimisation & Efficacy 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 healthcare professionals understand the term 'dietary supplement'
- 4. Marketing can be aimed at both the public and the professional.

<sup>\*</sup> Dietary Supplements 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						<b></b>		
Partnering discussions		7////					<b>——</b> )	*

## **Investment Summary**

- GaRP a large addressable and growing market and rapid development path
- Anatara has the funds necessary to progress GaRP through to a partnering deal in 2020
- Anatara has initiated discussions with sector specialists to maximise the commercial potential of a GaRP partnering deal
- Anatara will further strengthen the Board & Management
- Anatara aims to broaden its GI pipeline through collaborations and possible in-licensing opportunities



## Thank you

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