





Bringing Science to Supplements

December 2018



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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.



Anatara Corporate History

Global License with Zoetis for Detach for livestock and horses

Human Health Directors Appointed – Dr Jane Ryan & Sue MacLeman, Chair

Product Development Advisory Board established



Zoetis Option

Expand Management Team

Melbourne lab established

Key Management & Board of Directors



Steve Lydeamore, CEO

- 25+ years international pharmaceutical experience in Australia, USA and Canada
- Lead roles in global business development, manufacturing and finance, including the commercialisation of numerous consumer drug products
- MBA, CPA, GAICD



Dr Michael West, COO

- 25+ years in the pharmaceutical industry internationally
- Medicinal chemist with lead roles in drug discovery, drug development and manufacture
- Qualified Patent and Trademark Attorney



Dr Tracey Brown, CDO

- 20+ years experience in biotechnology and pharmaceutical product development – from conception to registration and reimbursement
- Lead roles in research institutions in USA & Australia
- Assoc Prof Monash University research commercialisation





Sue MacLeman, Chair

- 30+ years pharmaceutical, biotechnology and medical technology experience in corporate, medical, commercial and business development
- Has served as CEO and Board member of several ASX and NASDAQ listed companies
- MBA, LLM, ATSE Fellow, AICD

Dr Tracie Ramsdale, Director

- 30+ years drug discovery, design and development experience
- Multiple corporate financing transactions and product licensing deals with global pharmaceutical and manufacturing companies
- MPharm, PhD, ATSE Fellow, AICD

Dr Jane Ryan, Director

- 30+ years international experience in the pharmaceutical and biotechnology industries
- VP Product Development & Strategic Marketing and Director of Business Development at Biota Holdings Ltd (Relenza)
- Led multiple successful fundraising campaigns and licensing initiatives including the awarding of a \$230m US Gov contract

Key Financial Details

ASX Code ANR	Market Capitalisation ¹ \$22.2 million	Share Price ¹ \$0.45		
Current Cash ²	Ordinary Shares	Options		
\$7.1 million	49,413,236	2,346,000		

1. As at 30 November 2018

2. Appendix 4C - 30 September 2018

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Company Highlights

- Negotiated an exclusive global licensing agreement for the worldwide development, distribution and marketing of Detach with Zoetis Inc - leading global animal health company
- Detach received regulatory approval from Australian Pesticides and Veterinary Medicines Authority (APVMA) for use in piglets
- Growth in Anatara's skill set, with key appointments with significant human health experience:
 - Sue MacLeman and Dr Jane Ryan, to the Board of Directors, and
 - Steven Lydeamore as CEO

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

Animal Health

- Detach is a natural, safe, non-antibiotic product that **aids in the control of diarrhoea** (known as scour) in livestock
- In May 2018, Anatara 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%
- In October 2018, the Australian Pesticides and Veterinary Medicines Authority (APVMA) registered Detach for use in piglets in Australia













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 diarrhoea





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

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 diarrhoea
- Patients have a poor quality of life and utilise the healthcare system more than other patients
- ~50% of patients² turn to dietary supplements and complementary medicines



Percentage of overall adult population in each region who have IBS



IBS is the most commonly diagnosed gastrointestinal condition and a significant health care burden

¹ Clinical Gastroenterology and Hepatology 2012: 10, 712-721 ² World J. Gastroenterol 2014: 346-362

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 diarrhoea
- Treatment involves suppressing inflammation with the goal of inducing and maintaining remission
- 30-50% of IBD patients⁴ turn to complementary and alternative medicines



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.

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The Microbiome and IBS/IBD

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





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

- ~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

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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

leum Colon

Dual targeted product combining bromelain and other GRAS components*

lleum 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 diarrhoea

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 relevant animal disease models

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		\checkmark						
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 Anatara's research and product development programs in gastrointestinal health.









Thank you

