

Anatara Lifesciences Ltd

# Investor Presentation



**ANATARA**  
LIFESCIENCES



May 2023  
ASX: ANR

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# Specialising in the Gastrointestinal Tract

Evidenced-based solutions for gastrointestinal tract health issues



## About Anatar

Anatara Lifesciences Ltd (ASX:ANR) is focused on the validation and commercialisation of innovative, evidence-based products for human health with significant unmet needs with a focus on gastrointestinal considerations.

The Company is in the later stages of its pivotal clinical trial for irritable bowel syndrome with the patented GaRP product, with interim results due Q3CY23.

Additionally, there are a number of other indications for the use of GaRP and Anatara is actively assessing other opportunities in the healthcare space.

## Corporate Snapshot (05/05/2023)

ASX Code	ANR
Share Price	\$0.03
Shares on Issue	~119.9m
Market Capitalisation	~\$3.6m
Cash (Mar 31 2023)	~\$1.1m
<b>Enterprise Value</b>	<b>~\$2.5m</b>

## Investment Highlights

### Novel Technology

- Gastrointestinal Reprogramming (GaRP) technology aimed at restoring and maintaining gut health.

### Active pivotal clinical trial – Irritable bowel syndrome

- Primary Endpoint – Efficacy of ‘GaRP’ for irritable bowel syndrome**
- Interim results anticipated 3Q CY2023, full results anticipated 4Q CY2023

### Significant market opportunities

- US\$12.5B market for digestive health products in US<sup>1</sup>
- >US\$1.0B market for irritable bowel syndrome in US<sup>2</sup>

### Significant unmet medical need

- Treatments for IBS/IBD are not effective in controlling symptoms
- GaRP addresses the underlying factors of gastrointestinal disorders, providing multi-faceted symptomatic relief

### GaRP Technology to provide a pipeline of products

- Potential to apply GaRP to Inflammatory Bowel Disease (IBD), Paediatric indications & Functional Dyspepsia

### Assessing additional corporate opportunities

- Potential to acquire/license innovative assets/programs



# Gut Health promotes general wellbeing



## Gut Brain Axis & Mental Health

The gut and the brain communicate with each other through a complex network of nerves, hormones, and chemical messengers.

### A healthy gut can have significant benefits:

- ✓ **Improved Mood:** Having a healthy gut can help maintain optimal levels of neurotransmitters (serotonin and dopamine), which can contribute to improved mood.<sup>1</sup>
- ✓ **Reduced Anxiety and Depression:** An imbalanced gut microbiome has been linked to an increased risk of anxiety and depression. A healthy gut can help reduce the risk of these mental health conditions.<sup>2</sup>
- ✓ **Enhanced Cognitive Function:** A healthy gut with a balanced microbiome can produce various molecules, that can support brain health and cognitive function.<sup>3</sup>
- ✓ **Enhanced Nutrient Absorption:** Absorption of essential vitamins and minerals is improved by a healthy gut.<sup>4</sup>



## Wellbeing & weight management

Gut health influences a range of weight management-related body functions

### A healthy gut can have significant benefits:

- ✓ **Weight management:** Enrichment of bacterial genes and reduced diversity in the gut microbiome has been linked to obesity.<sup>5,6</sup>
- ✓ **Appetite Control:** Microbes in the digestive system produce metabolites that help regulate appetite and body fat stores.<sup>7</sup>
- ✓ **Reduced Inflammation and Blood Sugar:** Imbalances in the gut microbial community are associated with increased inflammation and increased blood sugar levels.<sup>8</sup>
- ✓ **Improved Nutrient Absorption:** Efficient absorption of essential nutrients, which can help optimize metabolism and energy production.<sup>4</sup>
- ✓ **Regulation of Metabolism:** A balanced Microbiota affects the regulation of metabolism which is closely linked to weight management.<sup>9</sup>



## Other diseases influenced by gut health

**Cardiovascular Disease** Growing evidence of links between microbiota and cardiovascular disease.<sup>10</sup>

**Autoimmune Diseases:** Maintaining healthy immune homeostasis can help assist autoimmune diseases by minimising dysregulation.<sup>11</sup>

**Cancer:** Bacteria inside the gut can positively assist cancer & cancer treatment throughout the body.<sup>12</sup>

<sup>1</sup> Appleton J. The Gut-Brain Axis: Influence of Microbiota on Mood and Mental Health. *Integrative Medicine*. 2016; 17(4):26-32.

<sup>2</sup> Clapp M, Aurora N, Herrera L, Bhatia M, Wilen E, Wakefield S. Gut Microbiota's Effect on Mental Health: The Gut-Brain Axis. *Clinics and Practice*. 2017; 7(4):987. <https://doi.org/10.4081/cp.2017.987>

<sup>3</sup> Tooley KL. Effects of the Human Gut Microbiota on Cognitive Performance, Brain Structure and Function: A Narrative Review. *Nutrients*. 2020; 12(10):3009. <https://doi.org/10.3390/nu12103009>

<sup>4</sup> Kojima K, Brown, Rosa et al. "Effects of gut microbes on nutrient absorption and energy regulation." *Nutrition in clinical practice: official publication of the American Society for Parenteral and Enteral Nutrition* vol. 27:2 (2012): 201-14;7

<sup>5</sup> Turnbaugh, P., Ley, R., Mahowald, M. et al. An obesity-associated gut microbiome with increased capacity for energy harvest. *Nature* 444

<sup>6</sup> Le Chatelier, E. et al. Richness of human gut microbiome correlates with metabolic profile. *Nature* 500:581-584 (2019).

<sup>7</sup> Han, H., Yi, B., Zhong, H. et al. From gut microbiota to host appetite: gut microbiota-derived metabolites as key regulators. *Microbiome* 9, 162 (2021).

<sup>8</sup> G  rard Celine, Vidal Hubert. Impact of gut Microbiota on Host Glycemic Control. *Frontiers in Endocrinology*. 10, 2019

<sup>9</sup> Oliphant, K., Allen-Vercoe, E. Macronutrient metabolism by the human gut microbiome: major fermentation by-products and their impact on host health. *Microbiome* 7, 91 (2019).

<sup>10</sup> Marco Witkowski, Taylor L Weeks, Stanley L Hazen. Gut Microbiota and Cardiovascular Disease. *Circulation Research*. 2020;127:553-570

<sup>11</sup> Shreiner, Andrew B.; Kao, John Y.; Young, Vincent B.B. The gut microbiome in health and in disease. *Current Opinion in Gastroenterology* 31(1):p 69-75, January 2015



# Key Management & Board of Directors

Highly experienced Board & Management



Anatara's nimble Board and Management structure provides significant experience and flexibility for potential corporate transactions.



**John Michailidis, COO**

- John is an executive with more than 30 years' of commercial pharmaceutical experience.
- His career has ranged from global franchise and regional executive leadership roles with F. Hoffman - La Roche to CEO experience with emerging biotechs.
- BSc (Hons) in Genetics from LaTrobe University and exec. business qualifications from Harvard Business School and INSEAD.



**Dr David Brookes, Executive Chair**

- 30+ years international experience in the health and biotechnology industries
- Former Chairman of genomics solutions company, RHS Ltd (ASX: RHS); acquired by PerkinElmer Inc (NYSE:PKI)
- Medical Practitioner, Biotechnology Consultant
- MBBS, FACRRM, FAICD



**Nick Haslam, Non-Executive Director**

- Nick is a chartered accountant with 10 years of experience in professional services within M&A and restructuring at PwC.
- Currently the CEO of Plasma Shield Limited, an Australian medical device company.
- Leadership roles within professional sports, which included scaling up KangaTech, a medical device and injury prevention business.



**Dr Jane Ryan, Non-Executive 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



# Gastrointestinal Health

GaRP progressing towards commercialisation



## Gastrointestinal ReProgramming (GaRP) technology for 'gut health'

### Active pivotal clinical trial – Irritable Bowel Syndrome

- **Primary Endpoint – Efficacy of 'GaRP' for irritable bowel syndrome**
- 140\* patient, placebo-controlled, dose-escalating pivotal trial
- Commenced Sept 2021; Interim readout 3Q CY2023; Final readout 4Q CY 2023

### Safety Profile

- All components GRAS (generally regarded as safe by FDA)

### Intellectual Property

- Patent pending formulation with functional coatings of synergistic combination of components

### Manufacturing

- GMP clinical batches manufactured and released for clinical trial

### Commercialisation via partnering

- Anatara is in discussions with potential global partners regarding exclusive agreements. The Company is experiencing in-bound interest regarding the clinical validation of GaRP

### Pipeline Indications

- Evaluating new indications for the GaRP technologies pipeline – in particular, inflammatory bowel disease, functional dyspepsia and paediatric indications.
- KOLs engaged



# Active Program

Anatara has multiple active programs approaching commercial outcomes



Program	Product	Indication	Population	Delivery	Discovery	Pre-Clinical		Clinical		Registration	Commercial Rights
						In-Vitro	In-Vivo	Proof of Concept	Pivotal		
Human	GaRP	Irritable bowel syndrome	Ages 18-65	Oral Minitabs	✓	✓	✓	3Q CY2023	4Q CY2023	Listed AUSTL Nos	Global

## Gastrointestinal ReProgramming (GaRP)

GaRP is a multi-component, multi-coated patented complementary medicine. It is designed to address the underlying factors associated with chronic gastrointestinal conditions such as IBS and IBD, in part by assisting to restore and maintain the homeostasis of the microbiome







GaRP

## One product, multiple benefits



**Patent Protected** - Scientifically designed to manage and control background IBS symptoms as well as episodic flare ups



Designed as an everyday option to manage the causes and relieve symptoms of IBS (pain, cramping, gas, bloating, diarrhoea & constipation)



Coated components released to the target areas for effective and sustained relief. 2 components release in the small intestine and 3 components have additional coating for delivery in the large intestine(colon).



Combines natural bromelain extract from pineapple stems in a patent pending formulation with other synergistic coated GRAS components

### Bromelain

Reduces pro-inflammatory cytokines & serotonin; promotes healing via mucin genes

### Menthol

Antispasmodic for smooth muscle GI Tract



GaRP

### Vitamin D

Improves mucosal barrier homeostasis and assists microbiome

### Butyrate

Supports gut barrier & restores homeostasis of microbiome

### Threonine

Amino acid that stimulates colonic healing



# Gastrointestinal ReProgramming (GaRP)

A potential breakthrough for gut health



Unique knowledge of bromelain's 'fingerprint'



Ingredients are GRAS



Well-characterised proprietary formula



Potential synergistic effects

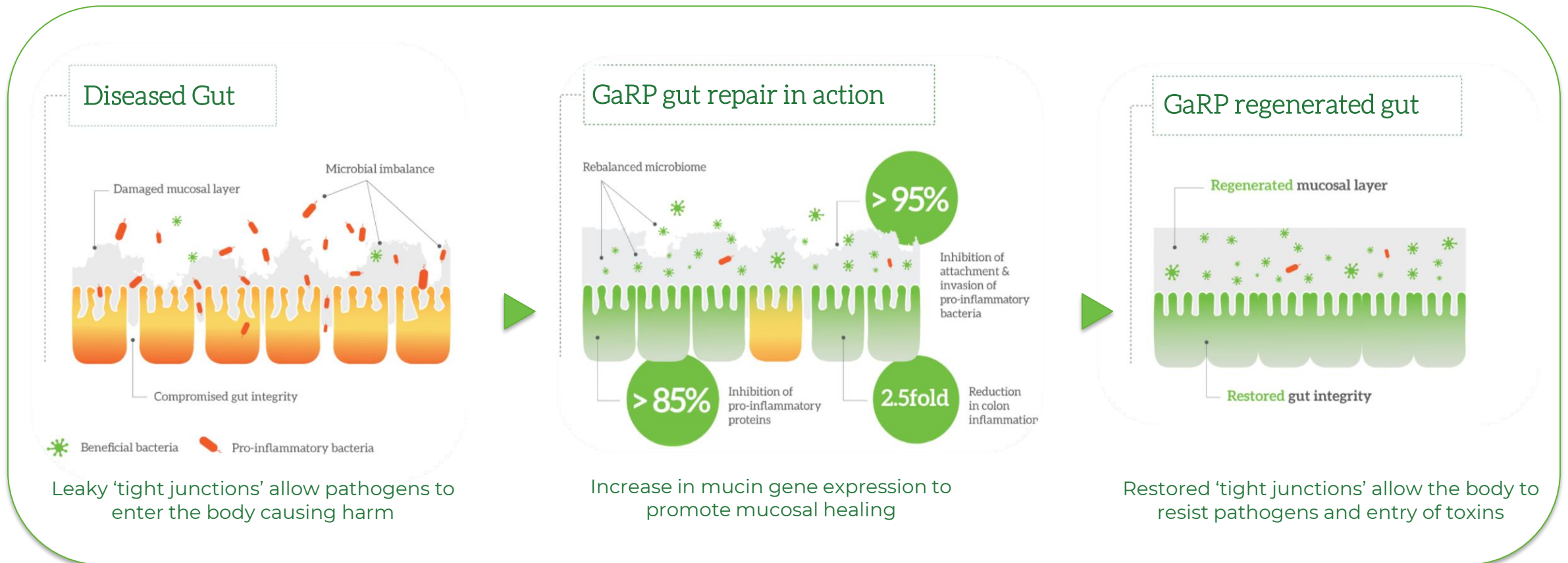


Gut-Brain Connection

	Function within formulation and potential impact on symptoms									
Quality Evidence Based Support IBS/IBD	Inhibitor of attachment / translocation of harmful bacteria	Restores homeostasis of gut microbiome	Influences metabolites of gut microbiome	Repairs 'leaky gut'		Reduction of diarrhoea		Modulates visceral sensitivity & intestinal motility	Assists immune system, brain health & mood	Safety Cautions
				Reduces gut-wall inflammation	Protection & regeneration of mucosa	Inhibits inflammation & secretory-induced	Serotonin induced (IBS)			
Pre-clinical ++ Pending clinical	✓	✓	✓	✓	✓	✓	✓	✓	✓	Nil :GRAS
✓				✓	✓	✓		✓		Warning: liver
Controversial-disputed, inconsistent	✓	✓	✓	✓		✓		✓	✓	
✓								✓		

# GaRP – Grounded in scientific evidence

GaRP addresses the underlying factors of gastrointestinal disorders



# Snapshot: IBS and IBD

Gastrointestinal disorders are highly prevalent and poorly managed

**IBS affects**  
**11%**  
**of the global population**<sup>6</sup>



## Debilitating Symptoms

Patients experience symptoms such as pain, bloating and diarrhoea



## Limited Treatments

Pharmacological options remain limited and often **leave patients with poorly controlled symptoms**<sup>8</sup>



## Frustrated Patients

**45%** of IBS-D patients agreed with the statement “I’m willing to try anything to help manage my IBS”<sup>9</sup>



## Patients seek alternative options

Up to **50%** of IBS/IBD patients use dietary supplements, complementary & alternative medicines<sup>10,11</sup>



## Doctors recommend supportive treatments

Health-care practitioners increasingly recommend the use of such supportive treatments<sup>12</sup>



## Iberogast recommended

For example, **source of recommended use of Iberogast: Healthcare provider 39.4%**<sup>13</sup>



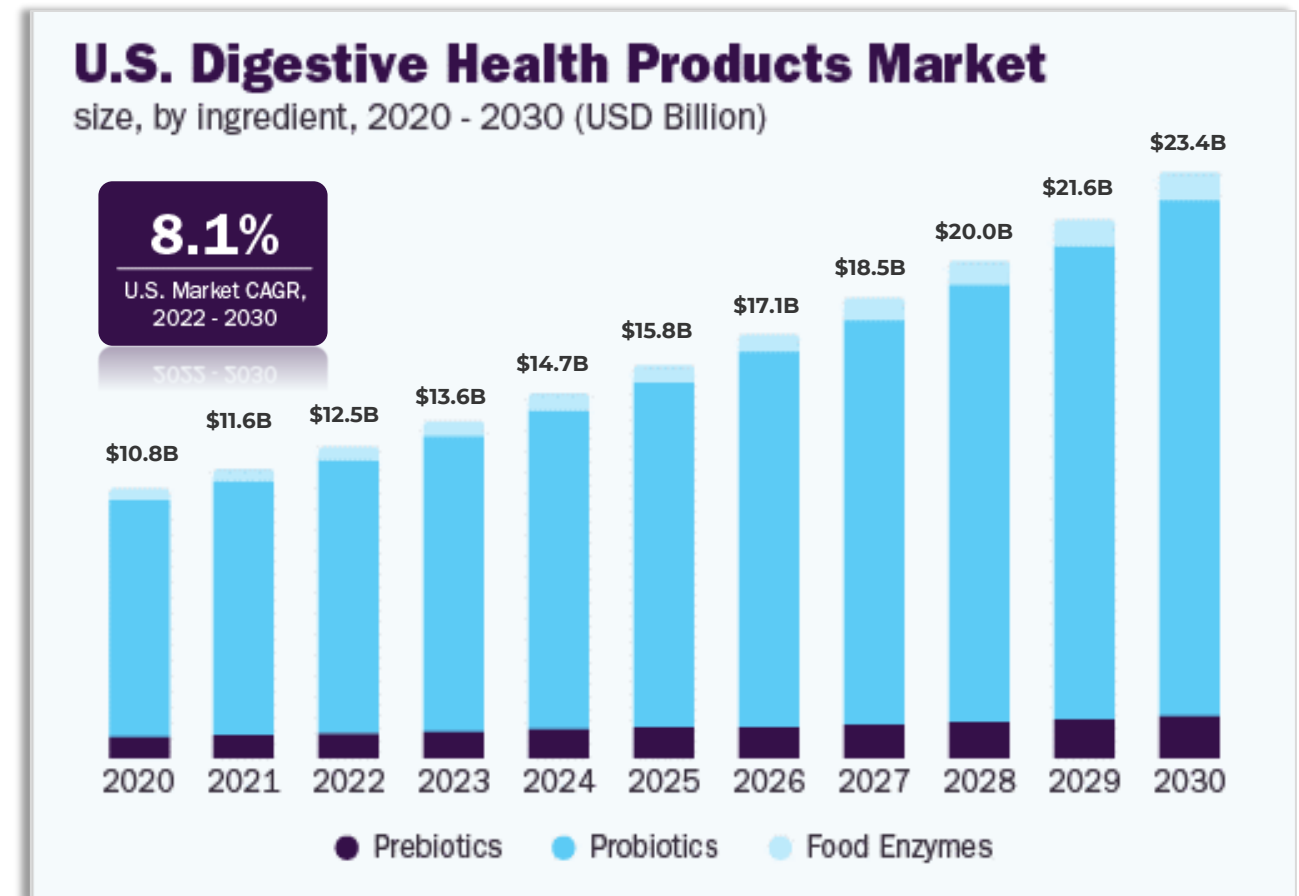
# Market Opportunity

The gut health market is significant, lacking effective, evidence-based solutions

## Digestive Health Market to be valued at US\$23.4B in 2030

### Growth rate of 8.1% to be sustained by:

- **High prevalence of disease** – Obesity, digestive disorders, and lifestyle-related diseases are likely to boost the demand for digestive health products globally.
- **Poor solutions** – There is no clear solution to gut health, resulting in consumers trying a vast array of options
- **Strong Thematic** - Growing demand for fortifying and nutritional food additives is one of the major factors driving the market.
- **Growing Awareness regarding:**
  - Improved health is motivating consumers to pay for better outcomes,
  - Maintaining gut health through a holistic approach to healthy living
  - Mainstream interest in product with potential to restore and maintain the gut lining & homeostasis of the microbiome





Source: <https://www.grandviewresearch.com/industry-analysis/digestive-health-products-market>

# Significant Corporate Interest

## Global Trend of Research & Development In Gastrointestinal Health

### Several examples of investment and/or collaboration by industry leaders in gastrointestinal health

Company #1	Stock Details	Company #2	Stock Details	Rationale of Deal	Agreement	Further Agreement
	SWX: NESN MKT CAP: A\$516Bn		Unlisted	<b>Nestlé</b> Health Science Partnering with French BioTech <b>Enterome</b> to develop and commercialise immunotherapies for food allergies and IBS.	€40M (Combination of Cash & Equity)	Clinical & Sales Milestone + Royalties on Sales
	PAR: SAN MKT CAP: A\$188Bn		Unlisted	Collaboration to provide a holistic approach to digestive health through combining the Gastrointestinal pharmaceutical knowledge of <b>Sanofi</b> with the digital health capabilities of <b>Cara Care</b> .	Agreement to Collaborate	N/A
	LSE: AZN MKT CAP: A\$270Bn		NAS: MCRB MKT CAP: A\$1.18Bn	Collaboration of <b>Seres Therapeutics</b> to research microbiome-based approaches to advance understanding of the efficacy of cancer immunotherapy, utilizing the extensive experience of <b>AstraZeneca</b> in oncology treatment.	Agreement to Collaborate	N/A
	ASX: SHL MKT CAP: A\$16.7Bn		ASX: MAP MKT CAP: A\$91.7M	<b>Sonic Healthcare</b> has completed a strategic investment in <b>Microba</b> to deliver their the individualised microbiome testing technology through Sonic's existing global pathology network.	\$17.8M Strategic Investment for a 20% stake	\$7.5M option for further investment
	ASX: IMC MKT CAP: A\$17.3m		Unlisted	<b>Immuron</b> has completed a strategic investment in <b>Ateria Health</b> to expand its offering in the "gut health" market through an IBS drug and expand their distribution.	\$2.6M Strategic Investment for a 17.5% stake	\$2.55M option for further investment









# Corporate/PE/VC Interest

Significant corporate interest in the wellness and gut health sectors

## Corporate Interest in the Wellness space

Acquirer	Stock Details	Target	Stock Details	Rationale of Deal	Agreement
	<b>TYO: 2503</b> MKT CAP: A\$21.9B	<b>BLACKMORES</b>	ASX:BKL	Japanese brewer <b>Kirin</b> acquired Australian vitamins maker <b>Blackmores</b> to diversify away from their extensive alcohol exposure and expand their wellness offering.	A\$1.88B
	<b>HKG: 1112</b> MKT CAP: A\$1.57B		Unlisted	<b>BioStime</b> acquired Australian vitamin maker <b>Swisse</b> Wellness to expand their beauty nutrition offering into new markets and expand their portfolio.	A\$1.67B

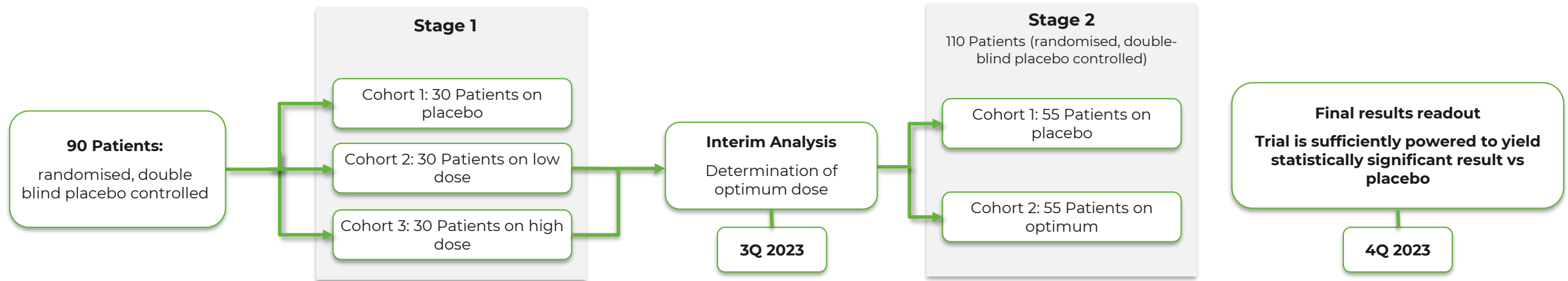
## Private Equity/Venture Capital Interest in Gut Health

Acquirer	Target	Rationale of Deal	Agreement
	<b>SYMPROVE</b>	Venture Capital & Private Equity firm <b>Bd-Capital</b> acquired <b>Symprove</b> , a company that is focused on delivering live and active bacteria to support the gut microbiome	Undisclosed Sum
 	<b>Pendulum</b>	<b>Pendulum</b> , a developer of medical probiotics addressing the imbalances of the microbiome raised \$54M lead by <b>Meritech Capital</b> as well as <b>Sequoia Capital</b>	\$54M capital raised for a \$111M total venture investment
	<b>B I O H M</b>	<b>Middleland Capital's VTC Ventures</b> led a \$7.5M raise on <b>Biohm Health</b> , a microbiome company with products designed to address the roles of bacteria and fungi in gut health.	\$7.5M capital raise
 	 <b>Peresphone Biosciences</b>	<b>First Bright Ventures &amp; Propel Bio Partners</b> raised \$15M in a seed financing round for <b>Peresphone Biosciences</b> researching therapeutic approaches for the microbiome including infant health and oncology	\$15M seed round
	<b>ZBIOTICS</b>	<b>Oyster Ventures</b> led a seed round of <b>ZBiotics</b> , a probiotic drink that breaks down the byproduct of alcohol responsible for hangovers for US\$2.3M	\$2.3M seed round



# Clinical trial – Irritable Bowel Syndrome

Robust clinical trial to validate the effectiveness of GaRP



**Title:** Dose Determination and Efficacy Evaluation of the Gastrointestinal ReProgramming (GaRP) Dietary supplement in IBS patients: A Randomized, Double-blind, Placebo controlled clinical trial

**Population:** Males and females 18-65 years of age with irritable bowel syndrome (IBS-SSS score of 175-350 and categorised as IBS on ROME IV criteria), two stages with interim analysis between stages with 90 in stage 1 and 110 in stage 2.

**Key Milestones & Messages:** 70 recruited; Safety expected as GRAS components; Interim readout 3Q 2023; study completion 4Q2023

## Primary Endpoints

- ✓ Treatment-Related Adverse Events
- ✓ IBS-Severity Scoring System (IBS-SSS) scale scores as continuous variable

## Exploratory Endpoints

- ✓ Plasma levels of specific inflammatory markers
- ✓ Comparison use of rescue medications between groups across study

## Secondary Endpoints

- ✓ Participants with reductions in IBS-SSS ; “responder” if  $\geq 20\%$  reduction to their baseline
- ✓ Change in IBS quality of life (IBS QoL) points compared to baseline
- ✓ IBS Adequate Relief (IBS-AR) compared to baseline
- ✓ Hospital Anxiety and Depression (HAD) Scale comparing to baseline

- ✓ Alterations in gut microbiota with respect diversity, perceived balance and correlation to IBS symptoms including overall wellness

# Licensing discussions & portfolio diversification

Progressing licensing discussions with global consumer health companies for GaRP



## Global Partners

Anatara is experiencing inbound interest from global leaders in the GI field due to the strong evidence based design of the GaRP trial.  
Discussions with global pharma companies are ongoing.

## Local Partners

Partnerships with regional leaders in 'gut' health to leverage local knowledge in registration and marketing of consumer health products and their established market position and infrastructure

## Partnership Opportunity: Interim Results

Potential for an earlier partnership if interim results for GaRP IBS study, anticipated in 3Q CY2023, indicate a strong trend towards a statistically significant benefit

**GaRP trial powered for significance**

## Partnership Opportunity: Post Trial

Following the anticipated completion of our IBS human trial in 4Q CY2023, Anatara expects to be in a strong position to announce a commercial partnership

**Revenue anticipated within 12 months from licensing**

# Pipeline Programs

Discussing licencing potential with producers and animal feed/nutrition companies

## Human Health

- Extensions for GaRP's broad indications for use-trial planning IBD paediatrics (synergistic effect of reduce immune suppressant dosing) & pilot Functional Dyspepsia
- Actively seeking in-licencing opportunities , M&A assets to broaden portfolio

## Animal health products

### Detach®, ANR-pf and BONIFF

- Orally administered, non-antibiotic products. Know how for products with extracts from pineapple stems for potential delivery in water or on feed mix. Unlike antibiotics and zinc oxide, will not contribute to antimicrobial resistance

### Transition away from zinc oxide

- Medicinal use of zinc oxide has recently been banned in EU (June 2022 <sup>19</sup>); indications others to follow (recent announcements in Canada <sup>20</sup> and Chile <sup>21</sup>). More than one-third of UK pig farmers were routinely using zinc oxide in pigs after weaning. <sup>22</sup>

### Validation Trials

- Poultry trials conducted with a leading Australian producer using ANR-pf (poultry) in broilers (chickens for meat production). This most recent trial delivered mixed results that suggested to both parties that a commercial product pathway requires further investigation. (UNE Jan 2021 positive study on efficacy ANR-pf performance broilers subject subclinical NE challenge)
- Murdoch University June 2021 trial report: Pigs fed the BONIFF-SMEC diet performed similarly to pigs fed the SMEC (semi-moist extruded creep transition feed) only diet comprising commercially relevant levels of ZnO and organic acids and phytogenic product.





# Advisory Board and DSMB members

Highly accomplished Advisory Board to guide ANR through to commercialisation

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.

Members include those pictured; noting the Data Safety Monitoring Board (DSMB) members are Professors Gibson and Rolan and Assoc. Prof. Begun.



Dr Tracey  
Brown



Associate Professor  
Rebecca Burgell



Professor  
Simon Keely



Dr Jeremy  
Rosenbaum



Associate Professor  
Jakob Begun



Professor  
Peter Gibson



Professor  
Paul Rolan



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# Glossary

<b>IBS</b>	Irritable bowel syndrome (IBS) is a condition that affects the colon (also referred to as “large bowel” or “large intestine”). Key symptoms include abdominal pain or discomfort, bloating, and chronic diarrhoea or constipation, or alternating between the two.
<b>IBD</b>	Inflammatory bowel diseases (IBD) are conditions in which the lining of the digestive gastrointestinal tract (GIT) becomes inflamed and damaged. The two common types of inflammatory bowel disease are Ulcerative Colitis and Crohn’s Disease. The most common symptoms of inflammatory bowel disease are: diarrhoea, often including blood &/or mucous, abdominal pain, loss of appetite, tiredness, fever, weight loss.
<b>ANR-pf</b>	Anatara’s proprietary enriched formulation for poultry in water, designed to allow the full delivery of key additives in a quick flexible dosing method on-farm even when stock illness is a concern.
<b>Bromelain</b>	Bromelain is a mixture of proteases extracted from pineapple stems. Specific proteases within Bromelain have wide activities influencing the GIT(Gastrointestinal tract)including anti-attachment, anti-secretory and reduction of pro-inflammatory factors. Collectively, these proteases provide a broad spectrum of activity from reducing the attachment of some diarrhoea-causing organisms to blocking inflammatory and adverse secretory factors.
<b>BONIFF</b>	Anatara’s recently developed in-feed bromelain-based formulation for weaner piglets.
<b>GaRP</b>	<b>G</b> astrointestinal <b>ReP</b> rogramming. Anatara’s GaRP product is a multi-component ,coated complementary medicine that has been designed to address underlying factors associated with chronic gastrointestinal conditions, such as IBS and IBD. This products is designed to assist restoration and maintenance of the GIT lining and the homeostasis of the microbiome.
<b>Leaky Gut Syndrome</b>	“Leaky Gut Syndrome” is a proposed condition associated with increased intestinal permeability that allows harmful substances (e.g toxins, bacteria) into the circulation which triggers adverse health effects through systemic inflammation and immune reactions. It is not considered a medical diagnosis and, while a very relevant consideration, it is not clear if it is a symptom or underlying cause of associated chronic diseases.
<b>GMP</b>	Good Manufacturing Practice. GMP describes a set of principles and procedures that when followed helps ensure that therapeutic goods are of high quality.
<b>GRAS</b>	Generally Recognised as Safe. A GRAS ingredient is an ingredient that has undergone safety evaluations by experts and has been proven not to cause harm when used as intended.