



**ANATARA**  
L I F E S C I E N C E S

**AGM**

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**ASX: ANR**



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## Developing the next generation of gastrointestinal health products

- More than ever, the world is looking for safe and effective solutions for gastrointestinal tract (GIT or 'gut') symptoms and disorders
  - **40% of global consumers say digestive complaints have had some influence on their lives<sup>1</sup>**
  - **Irritable Bowel Syndrome (IBS) is the most commonly diagnosed gastrointestinal condition and a significant cost burden on health care**
- The Anatara team is focused on delivering evidence-based treatments and solutions for gastrointestinal health needs in humans and animals
- Anatara aims to assist the homeostasis of the "gut" to promote overall health and wellbeing
- Commencing clinical trials in FY22, with fast potential speed to market
- Strong pre-clinical data for Inflammatory Bowel Disease (IBD)



<sup>1</sup> [https://nutraceuticalbusinessreview.com/news/article\\_page/A\\_good\\_gut\\_feeling\\_why\\_digestive\\_health\\_is\\_the\\_next\\_wellness\\_frontier/177171](https://nutraceuticalbusinessreview.com/news/article_page/A_good_gut_feeling_why_digestive_health_is_the_next_wellness_frontier/177171)

# Achievements

## Human health assets

### Achievements

- All components GRAS (FDA: generally regarded as safe)
- Patent pending formulation with functional coatings of synergistic combination of components
- Achieved clinical trial ethics approvals: GaRP and 3FDC
- GMP clinical batches manufactured and released for clinical trial
- Clinical trial – Irritable Bowel Syndrome
  - Commenced August 2021
- Clinical trial – Psychological Functioning
  - Commencing late November 2021

## Animal health assets

### Achievements

- Detach<sup>®</sup> patents granted in Australia and Japan
- Developed new bromelain-based formulations to offer convenient delivery options (in-feed, in-water) and for new species (poultry, aquaculture)
- ANR-pf: challenge trial in poultry for subclinical and necrotic enteritis successfully completed
- BONIFF + Ridley's SMEC: Challenge trial in piglets for enterotoxigenic Escherichia coli completed

# Program pipeline

PROGRAM			DELIVERY	DISCOVERY	PRECLINICAL		CLINICAL		REGISTRATION	COMMERCIAL RIGHTS
					In-Vitro	In-Vivo (animal)	Proof of Concept	Pivotal		
HUMAN	Irritable Bowel Syndrome (Diarrhoea)									
	GaRP	18-65	Oral Minitabs	✓	✓	✓	Mar '22	Sep '22		Global
	Moderate Depression, Anxiety or Stress									
	3FDC	15-55	Oral Minitabs	✓	✓	✓*		Apr '22		Global
ANIMAL	Scour (diarrhoea)									
	Detach®	Piglets	Oral Drench	✓	✓	✓	✓	✓	Australia (APVMA)	Global
	BONIFF	Piglets	Oral In-feed	✓	✓	✓	✓			Global
	Subclinical & Clinical Necrotic Enteritis									
	ANR-pf	Chicks	Oral In-water	✓	✓	✓	✓			Global



# Building a Health Portfolio

- Anantara aims to be the 'go to' company for gut health solutions, including treatments, diagnostics and advice
- Focused on delivering evidence-based treatments and solutions for GIT health needs

## **GaRP Technology to provide a pipeline of products**

- Potential to apply our GaRP technology into other GIT conditions, IBD in particular, and several largely unaddressed paediatric indications
- 3FDC is a combination of some components of GaRP used specifically for psycho-emotional indications

## **Presently evaluating diagnostics and other GIT therapeutic opportunities**

- To offer consumers and patients broader solutions to GIT complaints
- To diversify Anantara's portfolio of GIT health solutions
- We anticipate initiating one of these opportunities in the next 6 months



# Global consumer health market opportunity in managing gastrointestinal tract (GIT or 'gut') symptoms and general wellbeing is enormous

>US\$8 billion spend on OTC and digestive remedies alone <sup>2,3</sup>  
>US \$1 billion market in IBS alone <sup>4</sup>

## Probiotic supplements



Align® (P&G) sales  
(USA) 2018:  
**US\$172m<sup>4</sup>**

## Other GI supplements



Iberogast® (Bayer) sales  
(Germany) 2018: **€136m<sup>4</sup>**

## OTC digestive supplements



Buscopan® (Sanofi) sales  
(Global) 2020:  
**€177m<sup>5</sup>**

# GaRP technology

A potential break though for gut health



Unique knowledge of bromelain’s ‘fingerprint’



Ingredients are GRAS



Well-characterised proprietary mix



Synergistic effects



Gut-Brain Connection

Formulation Component	Function within formulation and potential impact on symptoms									
	Inhibitor of attachment/translocation of harmful bacteria	Restores homeostasis of gut microbiome	Influences metabolites of gut microbiome	Anti-inflammatory (T-cell & mast cell mediated factors)	Protection and regeneration of musoca	Reduction of diarrhoea			Modulates visceral sensitivity and intestinal motility	Promotes brain health and mood. Assists immune system pathways.
						Inflammation/ Secretory-induced	Non-inflammatory	Serotonin induced (IBS)		
Bromelain	✓	✓		✓		✓	✓	✓		
Entire Formulation (includes 3FDC)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓



## One product, multiple benefits



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  
such as pain, cramping, gas, bloating, diarrhoea and/or constipation



Coated components released to the target areas for effective and sustained relief



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





# Clinical trial – Irritable Bowel Syndrome (diarrhoea subtype; IBS-D)

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

**Population:** Males and females 18-65 years of age with irritable bowel syndrome (IBS-SSS score of 175-300 and categorised as IBS-diarrhoea subtype on ROME IV criteria), two stages with interim analysis between stages with 90 in stage 1 and 110 in stage 2.

**Key Milestones & Messages:** Commenced August 2021, Safety expected as GRAS components; Interim readout March 2022; study completion September 2022

## Endpoints

- ✓ Treatment-Related Adverse Events
- ✓ Safety markers
- ✓ Change in IBS quality of life (IBS QoL) points compared to baseline
- ✓ Change in IBS-Severity Scoring System between test and placebo groups compared to baseline
- ✓ Stool consistency (IBS-D) using the Bristol Stool Form Scale
- ✓ IBS Adequate Relief (IBS-AR) compared to baseline
- ✓ Hospital Anxiety and Depression (HAD) Scale comparing to baseline
- ✓ Catastrophizing questionnaire compared to baseline

## Exploratory endpoints

- ✓ Plasma levels of specific inflammatory markers
- ✓ Alterations in gut microbiota with respect diversity, perceived balance and correlation to IBS symptoms including overall wellness
- ✓ Changes in WPAI:GI\* compared to baseline



## Positively Influencing the Gut-Brain Connection



Aims to assist homeostasis of the “gut” to promote overall health and wellbeing



Targeting modulation of psychobiological processes driving anxiety-related disorders



Coated components released in the large intestine (colon) to positively influence the gut-brain connection



Combines synergistic, generally regarded as safe (GRAS) ingredients

# Clinical trial – Psychological functioning

**Title:** The effects of 3FDC dietary supplementation on psychological functioning in an adult population

**Population:** ~100 males or females 18-55 years of age with moderate levels of depression, anxiety, or stress symptoms indicated by the Depression, Anxiety and Stress Scale (DASS-21)

**Key Milestones & Messages:** Recruiting October; Safety expected as GRAS components; Study completion April 2022

Endpoints	<ul style="list-style-type: none"><li>✓ Clinically significant reduction in Hospital Anxiety and Depression Scale (HADS) scores</li><li>✓ Powered at ~95% to detect a clinically relevant reduction of <math>\geq 1.5</math> points in HADS scores from baseline to end of treatment (6 weeks) with significance set at 5% (<math>\alpha=0.05</math>; <math>\beta=0.95</math>; <math>f=0.15</math>)</li></ul>
Secondary outcomes	<ul style="list-style-type: none"><li>✓ Mood and wellbeing questionnaires</li><li>✓ Gut symptom ratings</li><li>✓ Blood plasma markers</li></ul>



# Commercialisation Strategy for GaRP Pipeline including 3FDC

## GaRP is a potential breakthrough, evidence based product

- targeting the cause of IBS, not just a product that treats symptoms

## Key markets

- North America, Europe, select Asia Pacific, select Latin American countries
- Lead indication IBS – market potential > US\$ 1 billion

## Commercialisation pathway for GaRP

- Progress human trials for GaRP and 3FDC
- Expand pipeline to cover additional indications
- Sign licensing deals in large key markets

## Expanding the GaRP pipeline

- GaRP pipeline expansion into IBD and paediatric indications will be considered following successful completion of the IBS study
- 3FDC pipeline expansion into other gut-brain axis conditions will be considered following successful completion of the mental health study

## Huge underlying demand given IBS prevalence across key markets

Region	Countries	IBS Prevalence <sup>2</sup> <sub>3</sub>	Population (M)	IBS Patients (M)
North America	USA	5-9.9% (7.5%)	327.2	24.5
	Canada	15-19.9% (17.5%)	37.6	6.6
EU	UK	10-14.9% (12.5%)	66.4	8.3
	Germany	5-9.9% (7.5%)	82.8	6.2
	France	0-4.9% (2.5%)	67.0	1.7
	Spain	10-14.9% (12.5%)	46.7	5.8
	Italy	5-9.9% (7.5%)	60.5	4.5
APAC	China	5-9.9% (7.5%)	1,386.0	104.0
	India	4-12.3% (7.3%)	1,339.0	97.7
	Japan	5-9.9% (7.5%)	126.8	9.5
	South Korea	5-9.9% (7.5%)	51.5	3.9
	Australia	10-14.9% (12.5%)	24.6	3.1
LATAM	Brazil	15-19.9% (17.5%)	209.3	36.6
Total IBS patients in key markets				312.4

# Licensing discussion progress and portfolio diversification

## **Anatara is progressing licensing discussions with international consumer health companies for GaRP and evaluating approach**

- 'Local Hero' licensing approach – forming partnerships with regional leaders in 'gut' health taking advantage of local knowledge in registration and marketing of consumer health products and their established market position and infrastructure
- Also in discussions with potential global partners in regards to exclusive agreements
- Potential for an earlier partnership if interim results for GaRP IBS-D study, anticipated in March 2022, indicate a strong trend towards a statistically significant benefit
- Following the anticipated completion of our IBS human trial in September 2022, we expect to be in a strong position to announce a commercial partnership
- ANR revenue generation anticipated within 12 months of licensing

## **Anatara will leverage know-how to address areas of unmet need in GIT health by providing solutions and advice**

- In FY22 Anatara will explore diversifying into additional gut health areas as it aims to become the "go to" gut health platform
- Key areas being explored include diagnostics and other GIT health therapeutics



# Glossary

<b>IBS</b>	Irritable bowel syndrome (IBS) is a condition that affects the colon (large bowel). Key symptoms include abdominal pain or discomfort, stomach bloating, chronic diarrhoea or constipation, or alternating between the two.
<b>IBD</b>	Inflammatory bowel diseases are conditions in which the lining of the digestive tract 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 anti-attachment, anti-secretory and anti-inflammatory activity. Collectively, these proteases provide a broad spectrum of activity by preventing the diarrhoea-causing organism from attaching to the small intestine and also by blocking inflammation and the secretory action of toxins.
<b>BONIFF</b>	Anatara's recently developed in-feed bromelain-based formulation for weaner piglets.
<b>GaRP</b>	<b>Gastrointestinal ReProgramming.</b> Anatara's GaRP product is a multi-component complementary medicine that has been designed to address the primary underlying factors associated with chronic gastrointestinal conditions such as IBS and IBD.
<b>3FDC</b>	A complementary medicine targeted to release predominantly beyond the ileocecal junction (boundary of the small and large intestines). The coated delivery of these 3FDC components to the large intestine is considered important for gut-brain axis balance, in part due to influences on microbiome homeostasis and metabolites. To be trialled in an upcoming human clinical study on changes to psychological functioning in adults with a moderate level of depression, anxiety or stress symptoms.
<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.

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