

Anatara Investor Presentation

MELBOURNE, 6 September 2021: Anatara Lifesciences (ASX: ANR), a developer of evidence based solutions for gastrointestinal diseases in humans and animals, is pleased to release to investors a copy of the presentation that Chief Executive Officer, Mr. Steven Lydeamore, will present today to investors.

A copy of the presentation is attached.

For more information please contact:

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About Anatara Lifesciences Ltd

Anatara Lifesciences Ltd (ASX:ANR) is developing and commercialising innovative, evidence-based products for gastrointestinal health where there is significant unmet need. Anatara is a life sciences company with expertise in developing products for human and animal health. Anatara is focused on building a pipeline of human gastrointestinal health products. Underlying this product development program is our commitment to delivering real outcomes for patients and strong value for our shareholders.

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

Investor Presentation

SEPTEMBER 2021

ASX: ANR



ANATARA
LIFESCIENCES

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**¹
 - **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 from Q1 FY22, with fast potential speed to market
- Strong pre-clinical data for Inflammatory Bowel Disease (IBD)



¹ https://nutraceuticalbusinessreview.com/news/article_page/A_good_gut_feeling_why_digestive_health_is_the_next_wellness_frontier/177171

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 ^{2,3}
>US \$1 billion market in IBS alone ⁴

Probiotic supplements



Align® (P&G) sales
(USA) 2018:
US\$172m⁴

Other GI supplements



Iberogast® (Bayer) sales
(Germany) 2018: **€136m⁴**

OTC digestive supplements



Buscopan® (Sanofi) sales
(Global) 2020:
€177m⁵

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 David Brookes, 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



Sue MacLeman, Non-Executive Director

- 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
- BPharm, LLM, MMkt, AICD, ATSE



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

Building a Health Portfolio

- Anataara 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 Anataara's portfolio of GIT health solutions
- We anticipate initiating one of these opportunities in the next 6 months



GaRP technology

A potential break though for gut health



Unique knowledge of bromelain’s ‘fingerprint’



Ingredients are GRAS



Well-characterised proprietary mix



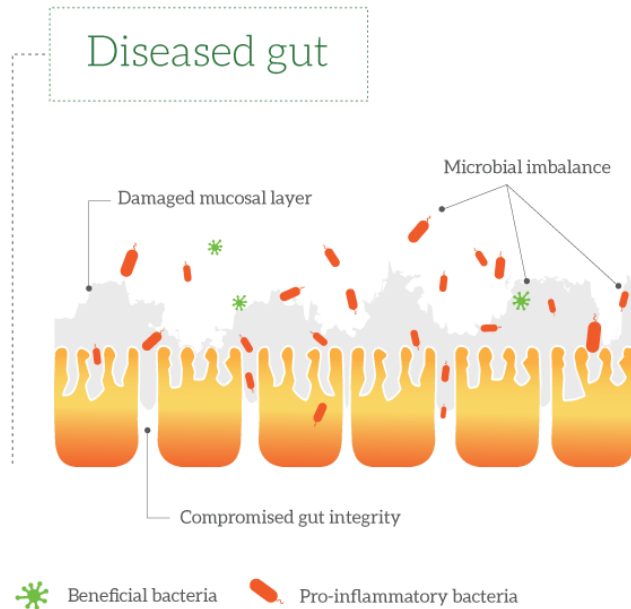
Synergistic effects



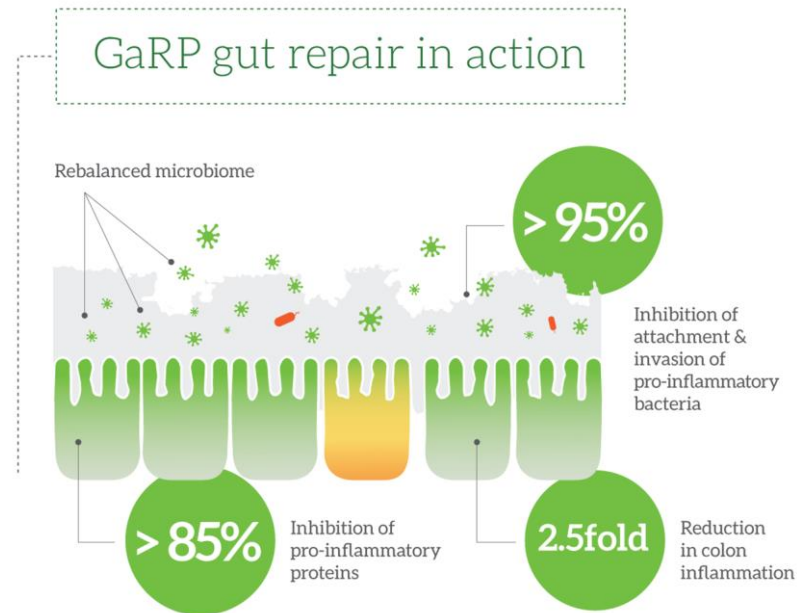
Gut-Brain Connection

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)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

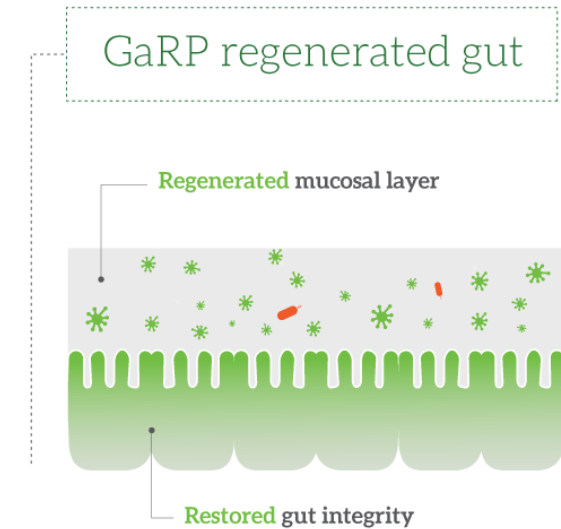
Grounded in scientific evidence



Leaky 'tight junctions' allow pathogens to enter the body causing harm



Increase in mucin gene expression to promote mucosal healing



Restored 'tight junctions' allow the body to resist pathogens and entry of toxins

Human Health

GaRP pipeline progressing towards commercialisation

- GaRP and 3FDC (3 components with functional delivery coating)
 - All components GRAS (FDA: generally regarded as safe)
 - Patent pending formulation with functional coatings of synergistic combination of components
- Ethics approved clinical trials: GaRP and 3FDC
- GMP clinical batches manufactured and released for clinical trial
- Clinical trial – Irritable Bowel Syndrome
 - **Commenced September 2021; Interim readout March 2022**
- Clinical trial – Psychological Functioning
 - **Commencing October 2021**
- Partnering discussions for GaRP and 3FDC: ongoing
- Evaluate new indications for GaRP/3FDC technologies pipeline



IBS and IBD in a minute

11%

IBS affects around 11% of the global population⁶

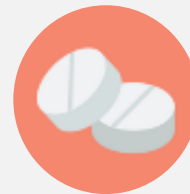


>5m

With accelerating incidence, IBD has an estimated >5million sufferers worldwide⁷



- Patients experience **symptoms** such as **pain, bloating and diarrhoea**
- Pharmacological treatment options remain limited and often leave patients with symptoms that are **not well controlled**⁸
- **45%** of IBS-D patients agreed with the statement “I’m willing to try anything to help manage my IBS”⁹



- Up to **50%** of IBS/IBD patients turn to **dietary supplements, complementary and alternative medicines**^{10,11}
- Health-care practitioners increasingly recommend the use of such supportive treatments¹²
- For example, **source of recommended use of Iberogast: Healthcare provider 39.4%**¹³



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: Recruiting now; Dosing from September, 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

Depression, Anxiety, Stress in a minute

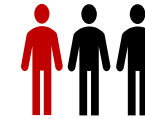
19%

19% of Americans have an anxiety disorder in any given year ¹⁴



38%

38.2% of the EU population met the criteria for a psychiatric disorder, <1/3 received treatment for it ¹⁵



- **19%** of Americans have an anxiety disorder in any given year; **31%** at some time of their lives ¹⁴
- Depression is a condition that affects about **1 in 10** U.S. adults ¹⁴
- **38.2%** of the EU population met the criteria for a psychiatric disorder, **<1/3** received treatment for it ¹⁵



- **24%** of U.S. adults with a mental illness report an unmet need for treatment ¹⁶
- **40%** of Americans treat themselves for mental health and overall wellness with complementary and alternative medicines (CAM) without professional supervision, often without disclosing it to their psychiatrist or primary care provider ¹⁷



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



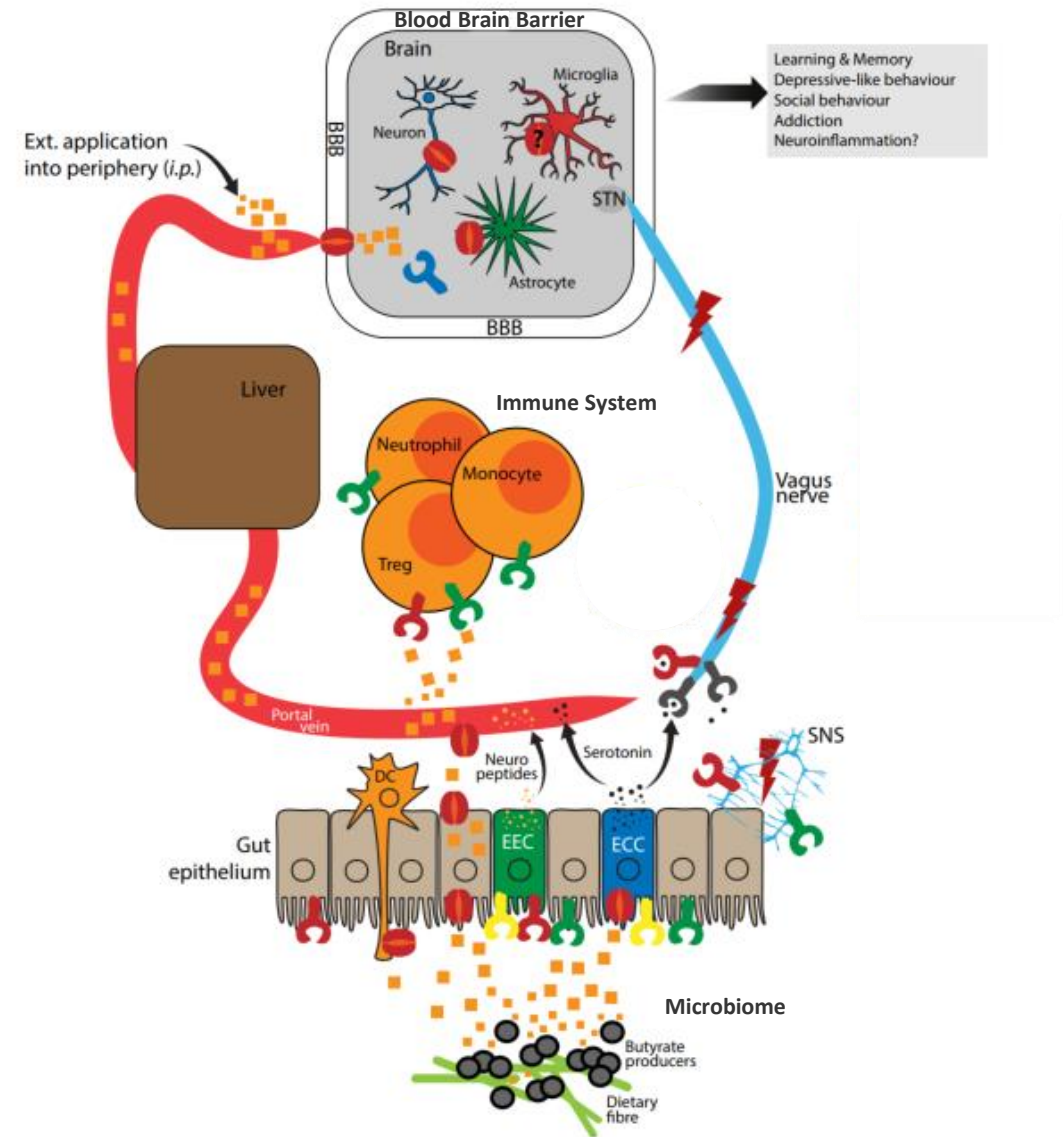
Coated components released in the large intestine (colon) to positively influence the gut-brain connection



Combines synergistic, generally regarded as safe (GRAS) ingredients

What is the gut-brain connection? ¹⁸

- The gastrointestinal system offers an integrated interface for regulation of various body functions in health and disease.
- The lining of the gut, known as the epithelium, is also the first line of defence against pathogens taken up with the diet. Due to the mutualistic nature of the majority of microbes in the gut, the gut epithelium is also the primary interface for host-microbe crosstalk on all levels of interaction.
- The immune system is trained and regulated by the presence of harmful and beneficial microbes, and products (incl. metabolites).
- Other than the vagus nerve involvement, any gut-brain interaction needs to cross at least two barriers (i.e. the gut epithelium and the blood brain barrier) and permeability through both of these barriers has been shown to be affected by the microbiome.



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



Animal Health

Portfolio progressing towards commercialisation

- Detach[®], ANR-pf and BONIFF
 - Orally administered, non-antibiotic products
 - Natural products extracted from pineapple stems
 - Unlike antibiotics and zinc oxide, unlikely to contribute to antimicrobial resistance
- Medicinal use of zinc oxide to be banned in EU in 2022 ¹⁹; indications that others will follow (recent announcements in Canada ²⁰ and Chile ²¹)
- More than one-third of UK pig farmers are still routinely using zinc oxide in pigs after weaning, and 60% have no plan in place for when it is banned in 2022 ²²
- BONIFF + Ridley's SMEC: Challenge trial in piglets for enterotoxigenic Escherichia coli successfully completed
- ANR-pf: challenge trial in poultry for subclinical and necrotic enteritis successfully completed
- Actively discussing with producers and animal feed/nutrition companies



¹⁹ <https://www.ema.europa.eu/en/medicines/veterinary/referrals/zinc-oxide#:~:text=What%20is%20zinc%20oxide%3F,post%2Dweaning%20diarrhoea%20in%20piglets>

²⁰ https://www.pigprogress.net/Piglets/Articles/2021/8/Canada-follows-the-EU-with-zinc-oxide-777113E/?utm_source=tripolis&utm_medium=email&utm_term=&utm_content=&utm_campaign=pig_progress

²¹ https://www.pigprogress.net/World-of-Pigs1/Articles/2021/1/Chiles-meat-sector-deal-for-antibiotics-usage-697251E/?utm_source=tripolis&utm_medium=email&utm_term=&utm_content=&utm_campaign=pig_progress

²² <https://www.fwi.co.uk/livestock/pigs/survey-highlights-pig-health-worry-ahead-of-zinc-oxide-ban>



Achievements and near term milestones

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

Near term milestones

- Clinical trial – Irritable Bowel Syndrome
 - Commenced September 2021; Interim readout March 2022
- Clinical trial – Psychological Functioning
 - Commencing October 2021
- Partnering discussions for GaRP and 3FDC: ongoing
- Evaluate new indications for GaRP/3FDC technologies pipeline

Animal health assets

Achievements

- 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;

Near term milestones

- ANR-pf: discussions with poultry producers and animal feed/nutrition companies
- BONIFF + Ridley's SMEC: discussions with pig producers and animal feed/nutrition companies

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
- Work towards licensing deals in local markets, while expanding pipeline to cover additional indications
- Sign further 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 ² ₃	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

Program pipeline

PROGRAM			DELIVERY	DISCOVERY	PRECLINICAL		CLINICAL		REGISTRATION	COMMERCIAL RIGHTS
					In-Vitro	In-Vivo (animal)	Proof of Concept	Pivotal		
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
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

Glossary

IBS	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.
IBD	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.
ANR-pf	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.
Bromelain	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.
BONIFF	Anatara's recently developed in-feed bromelain-based formulation for weaner piglets.
GaRP	Gastrointestinal ReProgramming. 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.
3FDC	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.
GMP	Good Manufacturing Practice. GMP describes a set of principles and procedures that when followed helps ensure that therapeutic goods are of high quality.
GRAS	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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