ASX Release

# Anatara Chairman Transition

MELBOURNE, 26 July 2021: Anatara Lifesciences (ASX: ANR), a developer of *evidence-based* solutions for gastrointestinal diseases in humans and animals, is pleased to announce the transition of Dr David Brookes from Non-Executive Director to Chairman. Sue MacLeman will continue on the Board, transitioning from Chair to Non-Executive Director.

The Board determined that, having successfully steered the Company following its decision to focus on the development of products and technologies in the human health sector with a focus on gut health, the time was now right for Dr Brookes to transition to the role of Chair as the Company progresses towards clinical trials.

CEO Steven Lydeamore said, "On behalf of the entire team at Anatara, I would like to acknowledge Sue's significant contribution to the Company as Chair over the past three years. Her transition to a Non-Executive Director role ensures we will continue to benefit from Sue's guidance as two separate human trials commence in the near future for our gastrointestinal complementary medicines GaRP and 3FDC."

Dr David Brookes has extensive experience in the health and biotechnology industries, first becoming involved in the biotechnology sector in the late 1990's as a consultant. Dr Brookes has since held Board positions in a number of ASX listed biotechnology companies, including as Chairman of genomicssolutions company, RHS Limited, which was acquired by PerkinElmer Inc (NYSE:PKI ). He is currently the Non-Executive Chairman of Factor Therapeutics (ASX: FTT), Non-Executive Director of Tali Digital Ltd(ASX: TD1), and Non-Executive Director of Island Pharmaceuticals Ltd (ASX:ILA).Dr Brookes maintains an interest in practicing medicine as a Fellow of the Australian College of Rural and Remote Medicine and in biotech consultancy. He was the non-executive Chairman of the private Better Medical Group until that company's sale to private equity firm Livingbridge in January 2021.

Commenting on his appointment as Chair, Dr Brookes said: "I am looking forward to the Chair appointment at such a pivotal time for Anatara, with the Company having made significant progress in developing evidence-based solutions for gastrointestinal disorders with an initial focus on the overall patient benefits to restoring gut homeostasis. The human trials are key next steps towards commercialisation of our products that are differentiated by an evidence- based approach to managing symptoms and disease modification. The unmet need is borne out by the wide range of products available for trial and error in the US$8+ billion gastrointestinal supplements and over-the-counter digestive remedies market[1]."

"I am very excited to oversee the active program we have in place particularly in the next 6 to 12 months that will progress the commercialisation of our health products, and to being able look at other opportunities to provide safe and effective solutions for gut health issues in humans and animals."

[1] Mintel's 2018 Digestive Health U.S. – July, 16; Nutrition Business Journal (NBJ)

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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.

ANATARA LIFESCIENCES

# Investor Presentation

## JULY 2021

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## ASX: ANR

**Advancing gastrointestinal health**

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# Corporate Fast Facts

ANATARA LIFESCIENCES

ASX ticker code

ANR

Share Price

$0.165*

Market Capitalisation

$11.6 million*

Ordinary Shares

70,238,523

Options

2,863,704

Performance Rights

780,985

## Board of Directors:

**Dr David Brookes**

**Sue MacLeman**

**Dr Jane Ryan**

## Management:

**Steve Lydeamore, CEO**

**Dr Michael West, COO**

## Product Development Advisory Board:

**Prof Jane Andrews**

**Dr Tracey Brown**

**Dr Rebecca Burgell**

**Prof Barry Campbell**

**Assoc Prof Simon Keely**

**Laureate Prof Nick Talley**

## Drug Safety Monitoring Board:

**Dr Jakob Begun**

**Prof Peter Gibson**

**Prof Paul Rolan**



* As at 23rd July 2021

# 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 pharmaceutical and biotechnology industries
- Former Chairman of genomics solutions company, RHS Ltd; 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

# Key Investor Message

- More than ever, the world is looking for safe and effective solutions for gastrointestinal symptoms and disorders
  - **59% of the global population experience digestive health issues once a week** *
  - **40% of global consumers say digestive complaints have had some influence on their lives** *
- Anatara aims to assist the homeostasis of the “gut” to promote overall health and wellbeing
- The Anatara team is focussed on delivering evidence-based treatments and solutions for gastrointestinal health needs in humans and animals



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

# Human health assets

**Achievements:**

- Achieved clinical trial ethics approvals: GaRP and 3FDC
- GMP clinical batches manufactured and released for clinical trial

**Activities planned for the next six months:**

- Clinical trial – Irritable Bowel Syndrome
- Clinical trial – Psychological Functioning
- Partnering discussions for GaRP and 3FDC: ongoing
- Evaluate new indications for GaRP/3FDC technologies pipeline
- Evaluate clinical ready gastrointestinal health product opportunities

# Global consumer health market opportunity

**US $8 billion**

**Gastrointestinal supplements and OTC digestive remedies in USA alone [1,2]**

### Probiotic supplements


Align® (P&G) sales (U.S.) 2018:
**US$171.9m**[3]

### Other GI supplements


Iberogast® (Bayer) sales (Germany) 2018:
**US$145m**[3]

### OTC digestive supplements


Buscopan® (Sanofi) sales (Global) 2018:
**US$220m**[4]

(OTC only, excludes prescription sales)



1. Mintel's 2018 Digestive Health U.S. – July, 16; 2. Nutrition Business Journal (NBJ); [3] Euromonitor International, Passport, Consumer Health 2019, [4] HBW Insights, February 2019

# IBS and IBD in a minute

**11%**

IBS affects around 11% of the global population[4]

**>5m**

With accelerating incidence, IBD has an estimated >5million sufferers worldwide[5]

- 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**[6]
- **45%** of IBS-D patients agreed with the statement "**I'm willing to try anything to help manage my IBS**"[7]

- Up to **50%** of **IBS/IBD patients turn to dietary supplements, complementary and alternative medicines**[8,9]
- Health-care practitioners increasingly recommend the use of such supportive treatments[10]
- For example, **source of recommended use of Iberogast: Healthcare provider 39.4%** [11]



[4] Clinical Gastroenterology and Hepatology 2012: 10, 712-721, [5] Crohn's and Colitis Australia, [6] Grundmann & Yoon 2010, [7] IBS Global Impact Report 2018 https://badgut.org/wp-content/uploads/IBS-Global-Impact-Report.pdf, [8] Gastroenterology 2017: 152:415-429, [9] World J. Gastroenterol 2014: 346 – 362, [10] Michelfelder, Lee, & Bading 2010 , [11] Yoon, Grundmann, Smith & Mason 2018

# GaRP technology

## A potential break though for gut health

**Ingredients are GRAS**

**Well-characterised proprietary mix**

**Synergistic effects**

**Unique knowledge of bromelain's 'fingerprint'**

| Formulation Component | Function within formulation and potential impact on IBD/IBS symptoms | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | Inhibitor of attachment/translocation of pathobiont bacteria | Restores homeostasis of gut microbiome | Anti-inflammatory (T cell & mast cell mediated factors) | Protection and regeneration of mucosa | Reduction of diarrhoea | | | Modulates visceral sensitivity and intestinal motility |
| | | | | | Inflammation/Secretory-induced | Non-inflammatory | Serotonin induced (IBS) | |
| **Bromelain** | ✓ | ✓ | ✓ | | ✓ | ✓ | ✓ | |
| **Entire Formulation** | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |

# Building a Gut Health Portfolio

- **GaRP – Irritable Bowl Syndrome**
- **3FDC – Psychological Functioning**

Potential to apply our GaRP technology into other gastrointestinal conditions caused by a disrupted microbiome, inflammation and mucosal damage.

- **Functional Dyspepsia**
- **Functional Diarrhoea**
- **Functional Constipation**

Evaluating complementary gastrointestinal diagnostic opportunities.

# GaRP

## “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
- Delivered straight to the problem areas for effective and fast relief
- Contains natural bromelain extract from pineapple stems and other natural ingredients

# Clinical trial – Irritable Bowel Syndrome

**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

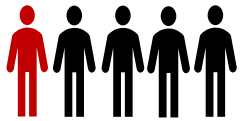
**Population**: Males and females 18-65 years of age with irritable bowel syndrome (IBS-SSS score of 175-300 and categorised as IBS-diarrhoea subtype on ROME IV criteria), two stages with interim analysis between stages with 90 in stage 1 and 110 in stage 2.

| | |
|---|---|
| **Endpoints** | ✓ Treatment-Related Adverse Events<br>✓ Safety markers<br>✓ Change in IBS quality of life (IBS QoL) points compared to baseline<br>✓ Change in IBS-Severity Scoring System between test and placebo groups compared to baseline<br>✓ Stool consistency (IBS-D) using the Bristol Stool Form Scale<br>✓ IBS Adequate Relief (IBS-AR) compared to baseline<br>✓ Hospital Anxiety and Depression (HAD) Scale comparing to baseline<br>✓ Catastrophizing questionnaire compared to baseline |
| **Exploratory endpoints** | ✓ Plasma levels of specific inflammatory markers<br>✓ Alterations in gut microbiota with respect to diversity and function, and if this modification is correlated to a reduction in IBS-D symptoms<br>✓ Changes in WPAI:GI compared to baseline |

# Depression, Anxiety, Stress in a minute

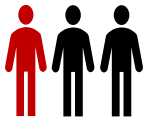
**19%**

19% of Americans have an anxiety disorder in any given year[12]



**38%**

38.2% of the EU population met the criteria for a psychiatric disorder, <1/3 received treatment for it[13]



- **19%** of Americans have an anxiety disorder in any given year; **31%** at some time of their lives[12]
- Depression is a condition that affects about **1 in 10** U.S. adults[12]
- **38.2%** of the EU population met the criteria for a psychiatric disorder, <**1/3** received treatment for it[13]

- **24%** of U.S. adults with a mental illness report an unmet need for treatment[14]
- **40%** of Americans treat themselves with complementary and alternative medicines (CAM) without professional supervision, often without disclosing it to their psychiatrist or primary care provider[15]



[12] National Center for Complementary and Integrative Health: https://www.nccih.nih.gov/health, [13] Wemrell M et. al (2020) Issues in Mental Health Nursing, Volume 41: https://doi.org/10.1080/01612840.2020.1744203,
[14] Mental Health America: https://www.mhanational.org/issues/state-mental-health-America, [15] Mental Health America: https://www.mhanational.org/sites/default/files/MHA_CAM.pdf

# 3FDC

- Improves and maintains gastrointestinal health in healthy individuals
- Assists patients manage their depression, anxiety and stress symptoms
- Effective relief
- Contains 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 with moderate levels of depression, anxiety, or stress symptoms indicated by the Depression, Anxiety and Stress Scale (DASS-21)

| | |
|---|---|
| **Endpoints** | ✓ Clinically significant reduction in Hospital Anxiety and Depression Scale (HADS) scores<br>✓ 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** | ✓ Mood and wellbeing questionnaires<br>✓ Gut symptom ratings<br>✓ Blood plasma markers |

# 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; statistical analysis and final report pending

**Activities planned for the next six months:**

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

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