ANATARA LIFESCIENCES LTD
Annual General Meeting – Chair's Address

Good morning, ladies & gentlemen, I am Dr. David Brookes, the Chair of Anatara Lifesciences Limited. Thank you for joining this virtual Annual General Meeting.

Before moving to the resolutions, on behalf of the Board, it is my pleasure to formally welcome you to the 2021 Annual General Meeting and to take this opportunity to provide an update on the Company's progress towards commercialising the Gastrointestinal ReProgramming product pipeline for human health, known as "GaRP", and unlocking the relevance of the animal health products. The Company has also become well placed to address broader gastrointestinal tract (GIT or "gut") human health issues and the significant unmet need for evidence-based solutions and advice for many sufferers of GIT symptoms and disorders.

GaRP is the working name for Anatara's *evidence-based* complementary medicine that includes unique formulations of bromelain, an enzyme extracted from pineapple stems, along with other synergistic GRAS[1] components. The combination and coating of these GaRP components have a beneficial effect on the physiology of the GIT lining, a positive influence on the microbiome (homeostasis & metabolites) and allow absorption of beneficial components in targeted areas of the GIT. GaRP's multimodal activity provides a versatility for tailoring the components to various indications and specifically this year we have progressed two human trials. The first is Anatara's GaRP trial studying the subset of Irritable Bowel Syndrome (IBS) with predominate diarrhoeal symptoms and recruitment for that trial commenced in October. The second trial is to be conducted by the CSIRO using several components of the GaRP combination (without bromelain) to study the effect on emotional well-being. Very importantly, there are further indications for the GaRP product that range from functional symptomatic relief to inflammatory bowel disease and with the potential for use in paediatric medicine.

I can confirm the GaRP trial is progressing to the revised timeline with significant broad interest and also that the CSIRO trial is anticipated to commence recruiting participants later this month. These trials are part of a strategy to differentiate our products as *evidence-based* and not just another supplement making health claims supported only by literature reviews of the studies of others or anecdotal trials. Anatara used pre-clinical *in vitro* models to determine the likely efficacy for each ingredient in the formulation of the GaRP combination. *In vivo* animal models demonstrated both safety and efficacy of GaRP in acknowledged gut models and this is now to be confirmed in human clinical studies.

The Company wishes to be clear on the robustness of the trial designs including that the Company is blinded from the results with initial results anticipated in April 2022. The CSIRO trial results are expected around that timeframe, as is the interim report on Anatara's GaRP study to confirm safety and tolerance, and to determine the dose strength to take forward into stage 2 of the trial. Continuation of the GaRP IBS study into stage 2 will indicate an expectation of a statistically significant efficacy result being possible and probable upon completion of the full trial.
There should not be speculation of Anatara having insight into the trial efficacy outcomes prior to the official notifications for the reasons already explained of robust, blinded trial designs. Our expectation for the trials is that safety is highly unlikely to be an issue given the GRAS status of the components and that while significant side-effects from the coating and combinations of the components are not anticipated, this needs to be confirmed by the trials. GaRP has been developed to be a breakthrough product that is an evidence-based treatment for not just symptomatic relief but to also address the underlying GIT imbalances that generate the symptoms.

While COVID had a significant impact on Anatara's programme, most directly by delaying the manufacturing of GaRP and the trial placebo, we have used that time to advance our understanding of other potential indications for GaRP as a complementary medication pipeline with variable coatings for delivery of up to 5 components. There are other significant indications for GaRP that we intend to address following the progression of the initial trials beyond the safety and tolerance milestones.
Additionally, we have turned our attention to broader GIT considerations and are looking at other opportunities to offer consumers and patients solutions to GIT complaints. With the trials unfolding, Anatara will upgrade our capacity for those interested to follow the company's progress and provide a forum for access to news and eventually advice. To address this, we have recently appointed an executive in the role of "Head of Business Development and Marketing Communications" to commence later this month to build on an overall reputation and outreach as a significant gut health company.

[1] Generally Recognised As Safe – US FDA designation that a substance is considered safe for use in food

(Details of the human trials and animal health products are included here for convenience and completeness, and will be addressed in the CEO's presentation)

Human Trials

Dose Determination and Efficacy Evaluation of the Gastrointestinal ReProgramming (GaRP) Dietary supplement in Irritable Bowel Syndrome -Diarrhoea subtype (IBS-D)

This randomised, double-blind, placebo-controlled study, commenced in August 2021, is being conducted in two stages as a virtual study. This involves minimal on-site visits and participants completing assessments online. Up to 6 sites will be established and approximately 200 participants enrolled. The study design consists of two stages with an interim analysis between stages. Stage 1 is anticipated to be completed in April 2022. Stage 2 is anticipated to be completed in September 2022.

Stage 1 will assess safety, tolerability, and be a guide to the efficacy of the two different strengths of GaRP used against a placebo, randomly divided in a protocol of 3 equal groups. Following interim analysis, one dose will be selected, and the remaining participants recruited in a 1:1 randomisation protocol. Of the 200 planned participants, at least 90 will enrol in stage 1, and 110 participants will enrol in stage 2. For each participant in each stage, the study will last for 12 weeks; including 8 weeks of treatment, preceded by a 2-week screening/baseline period, and followed by a 2-week washout period. Measurements will include a number of surveys including the IBS specific surveys: IBS-SSS (severity scoring system), IBS-AR (adequate relief) and Bristol Stool Form Scale. Other surveys will look at overall well-being, such as the IBS QoL (quality of life) and HADS (Hospital Anxiety and Depression Scale) in recognition of the importance of the gut-brain connection. The usual and expected clinical markers will all be monitored, including microbiome analysis.

Irritable Bowel Syndrome (IBS) is the most diagnosed gastrointestinal condition and a significant burden on healthcare. Over US$8 billion is spent annually on supplements and OTC digestive remedies in the US alone, presenting a huge market opportunity for Anatara. Our human health products will be built on strong scientific foundations for credibility and consumer confidence that provides a marketing distinction. The pre-clinical data to support the use of GaRP is very robust and our expectation is that this will translate in the human IBS-D trial. It is anticipated that GaRP's mechanism of action will relieve symptoms in IBS by reducing inflammation and assisting repair of the gut lining, and positively influencing the homeostasis and metabolites of the microbiome.

CSIRO trial –the "Gut-brain connection "using Anatara's 3FDC from GaRP pipeline

Anatara's GaRP pipeline not only addresses GIT homeostasis but more general harmony and well-being through influences on the gut -brain connection. In partnership with the CSIRO, Anatara is utilising "3FDC" as a specific complementary medication, coated to release in the large intestine, to explore the effect on depression, anxiety, and stress-related symptoms in otherwise healthy individuals. Again, the method of action implied is absorption of key components, a positive influence on the microbiome homeostasis and assisting the gut wall function."3FDC" is the Company's working reference to specific components from the overall GaRP product.

The study into the effects of 3FDC in adults with moderate anxiety, stress or depression is anticipated to commence recruiting patients in late November 2022 and expected to be completed by April 2022. This randomised, double-blinded, placebo-controlled study will be conducted at CSIRO's Nutrition and Health Research Clinic in Adelaide. Approximately 100 participants will be randomised in a 1:1 manner to treatment with 3FDC or placebo which is dosed twice a day for 6 weeks. Participants will be assessed at the start and end of the study period 'in-clinic' and will complete a series of questionnaires on a customised smartphone app over the duration of the study. In the event of tightening COVID-19 restrictions impacting 'in-clinic' visits, the study will transition to a virtual study with telehealth consultations. Such a transition is not anticipated to impact the primary outcome. The primary outcome is a clinically significant reduction in Hospital Anxiety and Depression Scale (HADS) scores. The study is 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%[2] . Secondary outcomes include mood and wellbeing questionnaires, gut symptom ratings and blood plasma markers.

In parallel with the trials progress, commercialization discussions continue for the GaRP pipeline products.

[2] **□ = 0.05; β= 0.95; f=0.15**

Animal Health

Antara's animal health assets were developed to control scour in piglets, a disorder which costs farmers worldwide millions of dollars every year. A current practice to control outbreaks is to administer zinc oxide to weaned piglet diets, however, its widespread use can result in risk to the environment through accumulation, and antimicrobial resistance similar to antibiotics. For these reasons, there has been a global trend towards reducing the reliance on zinc oxide and an increasing demand for a safe and effective non-antibiotic solution in piglets and other livestock. The use of medicinal zinc oxide to prevent diarrhoea post-weaning will be banned in the EU from 2022.

Our Detach® product is approved by the Australian Pesticides and Veterinary Medicines Authority (APVMA) for use in piglets in Australia. BONIFF is our bromelain-based in-feed formulation for piglets using Detach as the basis. We were encouraged by the results of the piglet challenge study in August 2021, which we aim to leverage to partner our bromelain-based animal health portfolio. The trial report concluded that BONIFF could be considered as a replacement for the current practice of using non-physiological levels of zinc oxide combined with commercial levels of additives in a semi-moist extruded creep piglet diet. While the commercial opportunity here is still being established, the initial indications are that BONIFF can be added to feed at a significant saving per tonne compared to the current regime of non-physiological levels zinc oxide combined with commercial levels of additives, such as organic acids.

Anatara's bromelain-based portfolio includes ANR-pf, which is a proprietary enriched formulation to address poultry gut illnesses, delivered in water. This is designed to allow the full delivery of key additives in a quick and flexible dosing method on-farm even when stock illness is a concern. Following successful completion of the poultry challenge trial "Efficacy of ANR-pf on the performance of broilers subject to subclinical and necrotic enteritis challenges", Anatara is actively seeking commercial partners.

Positive outlook for FY22

As you are aware, I was appointed as Chair of the Anatara Board in July, with Sue MacLeman transitioning to a Non-Executive Director role. I would like to take this opportunity to acknowledge Sue's significant contribution to the Company thus far, as Chair over a three-year period, and look forward to continuing to work with her and Dr. Jane Ryan as a small board focused and dedicated to rewarding shareholder patience and restoring value to the share price.
I would also like to acknowledge the service provided by Dr Tracie Ramsdale, who retired from the Board in October 2020 after six years, including a period where she acted as interim CEO, prior to Steve Lydeamore's appointment in 2019.

FY22 has the two human clinical trials underway this month after significant delays principally due to COVID-19 considerations. These trials will, of course, strongly influence both our commercial discussions and the plans for the use of the GaRP pipeline across other GIT indications. We look forward to working through these outcomes and will be looking to expand Anatara's position and profile as an emerging leader in evidence-based GIT health solutions. I would like to thank our team for their dedicated efforts during FY21 particularly given the challenges and frustrations faced with the pandemic and to thank my fellow Directors for their guidance and insights.

The efforts of the management team in recent years to create value around the Anatara IP with innovative formulations should be acknowledged as Anatara moves beyond the development phase of these products. It is opportune to announce now that our Chief Operations Officer, Michael West, is soon to depart and is assisting with a management transition to a newly appointed Chief Development Officer. On behalf of the Company, I take this opportunity to wish him all the best for the future and to express our appreciation of his contribution and for his ongoing involvement to ensure a seamless handover.

Following the capital raising activities in late 2021, which in total raised $2.86 million (net of costs), Anatara enters the 2022 financial year with a strong balance sheet well-funded to progress the 2 human trials using the GaRP pipeline (IBS-D and 3FDC in psychological functioning) and to assess other opportunities.

On behalf of the Board, I would like to thank our shareholders for their continued support and look forward to the progress through FY 2022, with a trials update anticipated early in the New Year.

Dr. David Brookes
Chair, Anatara Lifesciences Limited