## **ASX** Release



# 2022 Annual General Meeting – Chairman's Address



Dear Shareholders,

Thank you for your continued support and investment in Anatara Lifesciences. On behalf of the Board of Directors, I am pleased to present Anatara's 2022 Annual Report.

As you are aware, I became Executive Chairman of the Anatara Board in June 2022, upon the resignation of the Chief Executive Officer, Steven Lydeamore. This leadership change coincided with a critical assessment of the Company's assets, arrangements and a review of Anatara's trials

due to the struggling enrolment rates, despite broadening eligibility criteria. *I will further update the Company's progress today with important developments in the recent weeks following the Annual Report release in mid-October.* 

Anatara remains focused on the GaRP (Gastrointestinal ReProgramming multicomponent coated complementary medicine) Irritable Bowel Syndrome (IBS) 200 patient clinical trial which the Company continues to prioritise, striving to achieve interim results by no later than Q2CY2023. In line with the Company's vision, the IBS trial is consistent with developing innovative, evidence-based products for gastrointestinal health. There have been significant challenges and delays with the GaRP-IBS trial which we have addressed. These have been frustrating for all involved at Anatara, our shareholders and the many members of the community who have expressed interest in involvement, particularly those that have enrolled and not been able to further participate. I would like to take this opportunity to thank all those who have been involved or expressed interest and apologise for any inconvenience or frustrations, technical or otherwise.

Some of the earlier unforeseen challenges included the COVID-19 impact around the original trial commencement, which led to a late reorganisation of research organisations, and many operational and manufacturing disruptions from the pandemic not unique to Anatara. As we all know, emerging from the DELTA wave of the pandemic was far from the end with OMICRON then being a further dynamic that hampered progressing our trials for months. When able to have some consistency and continuity, the need for trial refinements became apparent including eligibility expansion requirements to accommodate the unique issues and challenges that sufferers of IBS deal with.

The Company remains optimistic in pursuing the GaRP-IBS study and to realise the commercialisation opportunities. The enrolment for Stage 1 of this trial is approaching 50% of the numbers required (90) in Stage 1 for interim analysis. There are currently approaching 40 enrolled with ongoing refinement of processes to enhance recruitment and conversion into participation. The interim analysis will be a pivotal near-term milestone for the Company. Completion of the GaRP-IBS interim phase without safety and tolerance concerns, and with an efficacy signal for dose selection into Stage 2, will have the

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Company well placed to address broader gastrointestinal health (GIT) indications for the use of GaRP. This will be consistent with our vision to address unmet needs for evidence-based solutions and advice for many sufferers of GIT symptoms and disorders.

The GaRP-IBS trial was broadened from including only the IBS-Diarrhoeal subtype to all IBS subtypes that sufferers experience, with the exception of the Constipation subtype. There was an apparent trial design issue in that participants that successfully went through screening could be "failed" in the baseline period before assignment to the study (i.e. to product or placebo). On September 1st, the Anatara Advisory Board was reconvened to look at this issue and the inclusion/exclusion criteria. The Advisory Board's recommendations to enhance the participation process and assist enrolment were consistent with Anatara's proposed strategies. We proceeded with ethics regulatory review for approval of these changes and intend to implement these re-defined criteria as soon as practical. These will accompany new communication methods to further enhance and accelerate recruitment which are anticipated to be in place in December. Pleasingly the changes to the inclusion/exclusion criteria have been approved by the relevant HREC (Human Research Ethics Committee) to most of our study sites with the Royal Melbourne Hospital HREC completing their process at present. We feel certain this will further enhance both enrolment and participation rates and experience without compromising the study.

A presentation on the GaRP trial will follow the business of the meeting to be given by Anatara's Clinical Trial's Manager, Kylie Wilkie, and with our Chief Operating Officer, John Michailidis and myself will respond to any questions.

There is strong mainstream support for a product that assists the restoration and functioning of the gut lining and the homeostasis of the microbiome. It has wider potential for medical indications, in particular inflammatory bowel disease (IBD), and in general use for relief of common GIT symptoms. The Company is confident that a positive interim readout in the GaRP-IBS trial will provide the foundation for broadening interest to other mainstream indications for the use of GaRP. Importantly, and as expected, with the use of a coated, combination of GRAS (Generally Recognised As Safe – US FDA designation that a substance is considered safe for use in food) components, there have been no safety nor tolerance concerns detected with the GaRP formulations including the subset of 3FDC.

As announced subsequent to FY2022, the trial with the CSIRO on the use of the 3FDC components of GaRP combination medicine for effect on psychological functioning was halted in September 2022. This study had been in the process of recruiting participants with mild to moderate levels of anxiety, depression or stress symptoms. During the review of all aspects of Anatara's trials, the Board elected to halt this study rather than commit to potential significant future costs on the balance of probability around a meaningful outcome. The GaRP complementary medicine includes a subset of 3 components formulated for release in the lower intestinal tract which have been labelled "3FDC". The GaRP -IBS trial has as secondary endpoints the Hospital Anxiety and Depression Scale (HADS) and Quality of Life (QOL) assessments. These will allow for preliminary analyses of the influence of the total GaRP components, in participants with gastrointestinal symptoms, on depression and anxiety. This anticipated insight regarding the relationship of anxiety and depressive symptoms with gut disorders (which is in keeping with the general interest in the gut-brain axis) may provide preliminary information about progressing the use of the full GaRP complementary medicine, which includes the 3FDC components, for these indications. The closure of the 3FDC trial has now been finalised (as of yesterday).

Given the broader indication opportunities for GaRP and the size of the gastrointestinal (GIT) health complementary medicine market, we remain committed to the GaRP trial as a project that can add substantially to overall shareholder value following a successful completion of the IBS trial. With confidence around the manufacturing specifications of GaRP as a complementary medicine, Anatara intends to seek licensing agreements and partnerships with established consumer health companies rather than contemplate direct marketing and distribution.

The review of Anatara's operations and projects confirmed the potential value and quality of the GaRP trial. It also cleared the perception of assets or otherwise allowing a capital raise to be considered to ensure the Company had sufficient funds beyond the GaRP-IBS trial Stage 1 interim analysis expected in Q2CY2023. The placement was strongly supported by existing and new shareholders, including new institutional shareholders, with the entitlement issue underway at present, as per ASX announcements. While it was disappointing to be raising capital in these circumstances, the Company had to ensure it was adequately capitalised to reach the near-term major milestone of interim data readout. I encourage shareholders to take up their entitlements to support the company in achieving its endeavours and to offset the dilutional consideration. The Company's stronger cash position also puts in good stead to review new commercial opportunities.

Anatara continues to critically assess other projects and assets predominately in or directly related to gastrointestinal health. Whilst the Company has progressed down the due diligence path on some of these assessments and continues to look at fresh opportunities, a compelling target project or asset has not been found at this point in time. In parallel, the business is establishing a marketing communications plan and customer strategy. This aims to promote interest in trial participation and results and the Company's activities in general, as we intend to develop a reputation as a trusted source of information and activities in gut health.

The use of Anatara's products in animal health present a promising but challenging potential, particularly in logistics of delivery and the variable efficacy seen so far. This has softened commercial interest from potential partners though we continue to discuss with interested parties the products for use in weanling pigs and poultry production. *Unfortunately, the most recent national and international expressions of interest in Anatara's bromelain-based animal products have currently concluded without a commercial outcome and suggestion that further evidence to support efficacy is required. We are still pursuing the opportunity that the global push for meat products free of antibiotics and animal husbandry not contributing to antimicrobial resistance provides, especially with Europe leading the way with a ban on zinc oxide (ZnO) as an additive being put in place in June 2022. <i>Anatara's BONIFF may yet have potential as a suitable replacement or additional supplement in weanling pigs*.

I would like to thank our small team for their dedicated efforts during FY22 particularly given the challenges faced. It has not been an easy period with delays and disappointments as outlined. Mr. John Michailidis has provided important input as Chief Operating Officer since joining to coincide with my commencement as executive chair in June of this year. I also thank my fellow Directors for their input, noting Board reviews and transition are part of ongoing governance with Ms. Sue McLeman having signalled her preference to retire from the Anatara Board around the time of the AGM. We all thank Sue for her contribution as a Board member and previous Chair, wishing her well with her future endeavours and many interests.

On behalf of the Anatara Board and management team, I offer our sincere thanks to shareholders, the clinical community and participating trial sites for their ongoing support. We remain motivated and

inspired to commercialise evidence-based solutions for gastrointestinal health and look forward to updating you on our progress.

Yours sincerely,

Dr. David Brookes

Executive Chair.

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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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