

ASX Release

Anatara Lifesciences 4C & Q1 FY25 Activities Report

Highlights for the Quarter

- **Recruitment is proceeding well for the second stage of Anatara's pivotal GaRP-IBS (Irritable Bowel Syndrome) trial with guidance updated to an expectation of Headline Results readout in Q1 CY2025.**
- **High levels of interest at 4 prioritised sites in Melbourne, Sydney, Adelaide and Sunshine Coast (QLD) with suitable numbers of potentially eligible candidates identified for the formal enrolment process.**
- **Announced Stage 2 trial updates including subsequently on 17th October that enrolment had reached 39 and, as of today, enrolment reached 43 with 30 in final screening.**
- **GaRP has been granted a European patent, expanding the intellectual property protection for the product. The granted patent is being validated in 19 major European countries plus the United Kingdom and provides protection until March 2039, with patent applications on-going in all major jurisdictions.**
- **Received in August an R&D tax incentive of \$626,806.72 for FY2024**
- **A General Meeting was held on 5th July 2024 at which shares in the Placement of \$1M from the previous Quarter were ratified and Director participation of \$70,000 was approved by shareholders.**

ADELAIDE, 31 October 2024: Anatara Lifesciences (ASX: ANR or "the Company"), a developer of evidence-based solutions for gastrointestinal diseases in humans, is pleased to provide a Quarterly update. Throughout the Quarter recruitment for the second stage of Anatara's pivotal GaRP-IBS (Irritable Bowel Syndrome) trial proceeded well and, to maintain and ensure momentum, 2 new trial sites in different geographical locations were established.

Stage 2 of the GaRP-IBS trial is the planned extension of the Phase II trial that follows the successful completion of Stage 1 involving 61 patients with a reported greater than a 50% reduction in IBS symptoms and with safety profile confirmed. Given the unmet need for an effective treatment for IBS, Anatara anticipates strong commercial interest in the ongoing trial of the effectiveness of the Company's patent protected product, known as "GaRP" (Gastrointestinal ReProgramming).



The Company's focus is on completing the recruitment for Stage 2 in Q4 CY2024 and, as previously advised in the ASX releases on 30th August 2024 and 8th October 2024, added two new locations to broaden participation in September. Recruitment in Adelaide at the South Australian Health & Medical Research Institute (SAHMRI) located on North Terrace in the city's health precinct and on Queensland's Sunshine Coast at the Coastal Digestive Health Research Institute (CDHRI) met with good interest and strong numbers into screening. Significant interest and activity continues across the other sites situated at the Royal Melbourne Hospital and Oztrials in Drummoyne (Sydney) with ongoing screening and enrolments.

To ensure ongoing overall trial efficiencies, the focus on recruitment has been prioritised to the 2 new sites and the 2 existing sites that are clearly demonstrating ongoing momentum in the enrolment process. This leaves 4 sites recruiting across the Eastern mainland states and Adelaide, SA. The other 3 sites are no longer involved in recruitment and continue to process enrolled participants per protocol.

The Company views the current level of trial activity across the sites as reassuring. Anatara is supporting all four sites via the Company's website and with social media promotions to ensure the momentum of the trial continues through to target recruitment levels that allow statistical analysis. The minimum target participant number for Stage 2 is 60 and, while the upper limit remains at 100, the Company anticipates that recruitment will be able to be ceased in the mid-range of the design for 60-100 Stage 2 patients.

Anatara Executive Chair, Dr. David Brookes commented in the ASX 30th August release that summarised the trial site changes in the Quarter: *"The additional trials sites provide the opportunity for IBS sufferers in further geographical locations to participate and will bolster enrolment to ensure adequate numbers through Stage 2 in the required time frame. We were encouraged by the eagerness of these new sites to be involved in the trial of our GaRP product as potentially an emerging treatment for a difficult medical condition and also by their empathy for the participants, given the GaRP-IBS trial criteria includes only moderate to moderately-severe sufferers by international classification in the IBS sub-types D (diarrhoeal predominate) and M (mixed). On behalf of the Company and the investigators and staff of the trial sites, we again take the opportunity to thank the participants and all those who expressed interest to be involved but did not meet the criteria to be enrolled."*

The target participant number is 60-100 for Stage 2 of the Trial and the Company anticipates this target number will be met before the end of Q4 CY2024 with Headline Results readout anticipated in Q1 CY2025.

Potential participants can find the closest site to register their interest in Stage 2 of the clinical trial at ibstrial.au or via the Company's website: <https://anataralifesciences.com/garp-clinical-trial/>

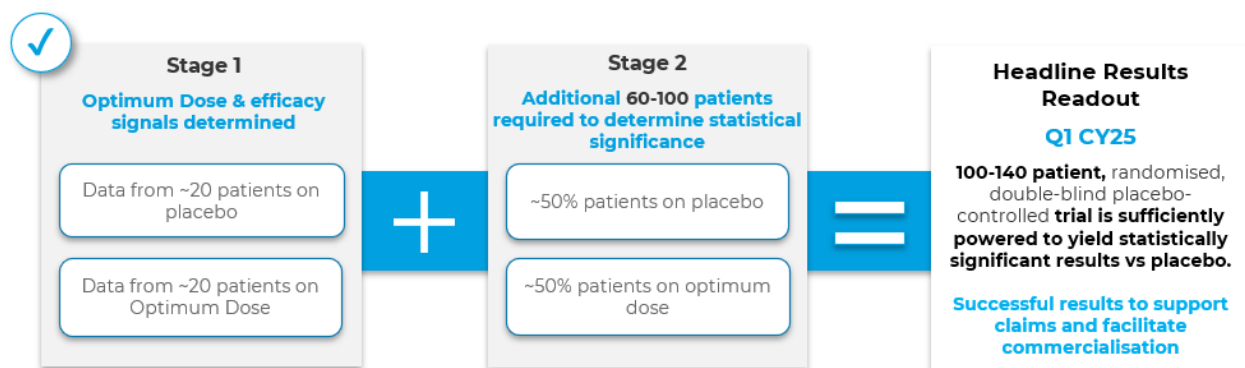
Participants will be randomised into one of two arms in the trial in a 1:1 ratio and receive either the optimum dose of the GaRP product selected from Stage 1 or placebo for 8 weeks plus 2-week follow-up.

Stage 2 aims to confirm the highly encouraging and clinically meaningful interim results from Stage 1 of the GaRP-IBS clinical trial. The data from Stage 1 and the 60-100 Stage 2 patients in the



randomised, placebo controlled, double blind trial will form the basis of the analysis. This will result in 100-140 patients in total. The trial is sufficiently powered to deliver statistically significant results versus placebo.

GaRP-IBS Clinical Trial Design



Ongoing Corporate Activities

On the 20th of September, the Company announced that notification of a decision to grant a European patent from the European Patent Office (EPO) for the title and documents relating to its Gastrointestinal ReProgramming product (known as “GaRP”) had been received. The decision from the EPO took effect from the publication of the grant in the European Patent Bulletin 24/38 on the 18th September 2024. The EU patent for GaRP has a patent number 4041285 and was filed on 9th October 2020. Priority is claimed to Australian patent application AUA 2019903822 filed on 11.10.19. Therefore, the date of expiry will be priority date plus 20 years, i.e. 11.10.2039.

Patent application processes for the GaRP product are ongoing and continue in a number of other jurisdictions, including the important USA market.

The results from Stage 1 signalled a promising new era in the quest to alleviate the burdens of IBS and related disorders. Confirmation of these results from Stage 2 of the trial will provide the desired evidence-based claim to distinguish GaRP as an IBS treatment and a more valuable foundation to engage with global pharma companies interested in expanding their portfolio of medicines for gastrointestinal and related disorders. Discussions remain ongoing with potential partners interested in delivering a new, safe and effective treatment for IBS into a highly unsatisfied market. Additionally, the Company continues to actively assess other opportunities in the human healthcare space and is appraising projects suitable to add to the Company’s portfolio.

The Company is securing a supply chain of materials for commercial readiness of the GaRP product and assessing manufacturing options for global commercialisation.

Summary Q1 FY2025 cashflows

The Company’s cash at the end of the quarter was \$0.923 million (30th June 2024: \$0.982 million). Net cash outflow from operating activities during the quarter was \$0.06 million, that included a \$50,000 fixed deposit, compared to a \$0.856 million cash outflow from



operating activities in the previous quarter. The cash flow is primarily related to the continuation of Stage 2 of the IBS Clinical Trial and the receipt of R&D tax incentive funds.

The aggregate payments to related parties and their associates during the quarter totalled \$72,000, which includes directors' fees and superannuation.

Anatara completed a successful capital raising of A\$1.0m in May 2024, reflecting strong support from existing institutional and sophisticated investors, with the issue price of \$0.04 being less than a 5% discount to the 5-day VWAP as at close of trade the day before raise. Director participation in the Placement of \$70,000 was approved by shareholders via an EGM on 5th July 2024 which finalised the capital raise process.

On 29th August, the company reported receipt of \$626,806.72 from the Australian Taxation Office under the Federal Government's Research and Development (R&D) tax incentive scheme for FY2024. This added to the Company's cash position and there are no debt or loan facilities in place nor contemplated.

Subsequent events

On the 2nd of October 2024, the Company issued notice of the AGM (Annual General Meeting) to be held in Adelaide on the 14th of November and released the Annual Report for FY2024.

Recruitment for the GaRP-IBS trial continued with good momentum through October 2024 with enrolment reaching 43 participants and a further 30 in final screening.

Other Corporate Activities

Anatara Lifesciences featured in the following news publications over the course of the quarter:

Yahoo Biz News - July 10th

<https://finance.yahoo.com/news/shining-spotlight-ibs-anatara-lifesciences-163000049.html?guccounter=1>

SmallCaps Article - July 30th

<https://smallcaps.com.au/anatara-lifesciences-on-track-recruitment-stage-2-garp-ibs-trial/>

SmallCaps Live Interview - September 13th

<https://youtu.be/wrjTH4309es>

About GaRP

Anatara's GaRP product is a multi-component, multi-coated complementary medicine designed to address underlying factors associated with chronic gastrointestinal conditions such as IBS and IBD. GaRP is the working name for the product from the Company's **G**astrointestinal **R**eProgramming project that was designed to assist restoration and maintenance of the gastrointestinal tract (GIT) lining as a barrier and assist the homeostasis of the microbiome. The product is made of GRAS (Generally Regarded As Safe) components.



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About Anatara Lifesciences Ltd

Anatara Lifesciences Ltd (ASX:ANR) is developing and commercialising innovative, evidence-based health products where there is significant unmet need. Anatara is focused on building a pipeline of human health products with a particular focus on conditions that involve the complexity of the gastrointestinal tract. Underlying this product development program is our commitment to delivering real outcomes for patients and strong value for our shareholders.

Disclaimer

The information in this presentation does not constitute personal investment advice. The presentation is not intended to be comprehensive or provide all information required by investors to make an informed decision on any investment in Anatara Lifesciences Ltd, ACN 145 239 872 (Company). In preparing this presentation, the Company did not take into account the investment objectives, financial situation, and particular needs of any particular investor. Further advice should be obtained from a professional investment adviser before taking any action on any information dealt with in the presentation. Those acting upon any information without advice do so entirely at their own risk. Whilst this presentation is based on information from sources which are considered reliable, no representation or warranty, express or implied, is made or given by or on behalf of the Company, any of its directors, or any other person about the accuracy, completeness or fairness of the information or opinions contained in this presentation. No responsibility or liability is accepted by any of them for that information or those opinions or for any errors, omissions, misstatements (negligent or otherwise) or for any communication written or otherwise, contained or referred to in this presentation. Neither the Company nor any of its directors, officers, employees, advisers, associated persons or subsidiaries are liable for any direct, indirect or consequential loss or damage suffered by any person as a result of relying upon any statement in this presentation or any document supplied with this presentation, or by any future communications in connection with those documents and all of those losses and damages are expressly disclaimed. Any opinions expressed reflect the Company's position at the date of this presentation and are subject to change.

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Appendix 4C

Quarterly cash flow report for entities subject to Listing Rule 4.7B

Name of entity

Anatara Lifesciences Ltd (ASX:ANR)

ABN

41 145 239 872

Quarter ended ("current quarter")

30 September 2024

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (3 months) \$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers	-	-
1.2 Payments for		
(a) research and development	(263)	(263)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	(52)	(52)
(d) leased assets	-	-
(e) staff costs	(177)	(177)
(f) administration and corporate costs	(226)	(226)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	2	2
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	627	627
1.8 Other (provide details if material)	29	29
1.9 Net cash from / (used in) operating activities	(60)	(60)
2. Cash flows from investing activities		
2.1 Payments to acquire or for:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	-	-
(d) investments	(50)	(50)
(e) intellectual property	-	-
(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (3 months) \$A'000
2.2	Proceeds from disposal of:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-
2.3	Cash flows from loans to other entities	-	-
2.4	Dividends received (see note 3)	-	-
2.5	Other (provide details if material)	-	-
2.6	Net cash from / (used in) investing activities	(50)	(50)

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	70	70
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	-	-
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(19)	(19)
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	-	-
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (provide details if material)	-	-
3.10	Net cash from / (used in) financing activities	51	51

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	982	982
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(60)	(60)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(50)	(50)

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (3 months) \$A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	51	51
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	Cash and cash equivalents at end of period	923	923

5.	Reconciliation of cash and cash equivalents at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	Current quarter \$A'000	Previous quarter \$A'000
5.1	Bank balances	923	932
5.2	Call deposits	-	50
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
5.5	Cash and cash equivalents at end of quarter (should equal item 4.6 above)	923	982

6.	Payments to related parties of the entity and their associates	Current quarter \$A'000
6.1	Aggregate amount of payments to related parties and their associates included in item 1	72
6.2	Aggregate amount of payments to related parties and their associates included in item 2	
<i>Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments.</i>		

Item 6.1 Reflects amounts paid to directors including director's fees, salaries, superannuation, bonuses and consulting fees (excluding reimbursements).

7.	Financing facilities <i>Note: the term "facility" includes all forms of financing arrangements available to the entity.</i> <i>Add notes as necessary for an understanding of the sources of finance available to the entity.</i>	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
7.1	Loan facilities	-	-
7.2	Credit standby arrangements	-	-
7.3	Other (please specify)	-	-
7.4	Total financing facilities	-	-
7.5	Unused financing facilities available at quarter end		-
7.6	Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.		

8.	Estimated cash available for future operating activities	\$A'000
8.1	Net cash from / (used in) operating activities (item 1.9)	(60)
8.2	Cash and cash equivalents at quarter end (item 4.6)	923
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	923
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	15.48
<i>Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.</i>		
8.6	If item 8.5 is less than 2 quarters, please provide answers to the following questions:	
8.6.1	Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?	
	Answer: N/A	
8.6.2	Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?	
	Answer: N/A	
8.6.3	Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?	
	Answer: N/A	
<i>Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.</i>		

Compliance statement

- 1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.
- 2 This statement gives a true and fair view of the matters disclosed.

Date: 31/10/2024

Authorised by: By the Board

Notes

1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.
2. If this quarterly cash flow report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report. If this quarterly cash flow report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.
3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.
4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [name of board committee – eg Audit and Risk Committee]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".
5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's *Corporate Governance Principles and Recommendations*, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.