

ASX Release

Anatara Lifesciences 4C & Q2 FY25 Activities Report

Highlights for the Quarter ending December 2024

- Recruitment was able to be paused on December 13th 2024 following satisfactory participation for the second stage of Anatara's pivotal GaRP-IBS (Irritable Bowel Syndrome) clinical trial, with guidance maintained of Headline Results readout in Q1 CY2025.
- 63 participants had enrolled into Stage 2 of the trial as announced in ASX update on 14th December and enrolment is confirmed as 71 ITT (Intent-To-Treat) participants, as of today.
- Trial participant numbers are in line with Company expectations with final patient number considerations currently being assessed with a view to Headline Results readout in March 2025.
- The Commercial opportunity for GaRP is significant given the global focus on gastrointestinal tract (GIT) health with the Digestive Health Market to be valued at US\$23.4B in 2030 with a CAGR of 8.1%.¹
- Received \$0.75M before costs from placement at \$0.05c in November 2024 and an additional \$0.274M was raised on the same terms via a Share Purchase Plan (SPP), leaving the Company fully capitalised beyond pivotal trial results readout and future milestones.
- Announced the commencement of an anti-obesity project with *in-vivo* proof-of-concept being prepared for ethics submission.
- AGM held 14th November 2024 and investor webinar 2nd December 2024

ADELAIDE, 15 January 2025: Anatara Lifesciences Ltd (ASX: ANR or Anatara or "the Company"), a developer of evidence-based, innovative products to address significant unmet need in human health, with a particular focus on conditions that involve the complexity of the gastrointestinal tract (GIT), is pleased to provide a Quarterly update. Throughout the Quarter, regular updates were

¹ <https://www.grandviewresearch.com/industry-analysis/digestive-health-products-market> 2. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7212496/>



provided on recruitment for the second stage of Anatara's pivotal GaRP-IBS (Irritable Bowel Syndrome) trial.

On the 13th of December 2024, the Company announced a recruitment pause for the trial with 63 participants enrolled and the ongoing processing of those identified as potential participants to be completed by the following week. Following that final week of processing, we now have an additional 8 enrolments actively involved in the trial, with the Stage 2 enrolment number confirmed as 71 Intent-To-Treat participants. The current trial participant numbers are in line with Company expectations and the usual activities are ongoing at the trial sites. The final patient number considerations are currently being assessed, with recruitment remaining in "pause."

Anatara's pivotal Phase II GaRP-IBS clinical trial is a randomised, double blind, placebo-controlled study of the highest quality and rigour and, assuming trial success, will provide an evidence-based validation for the GaRP product in IBS. This furthers commercial discussions for the product for IBS and opens the product use for a wide range of other GIT health indications. Trial success is a validation of GaRP's unique, complex mechanism of action of restoring and maintaining the GIT lining as a barrier while assisting the homeostasis of the microbiome.

Stage 2 of the GaRP-IBS trial is the planned extension of the Phase II trial that follows the successful completion of Stage 1 which reported on 61 patients with a 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" (from the Company's *Gastrointestinal ReProgramming* project).

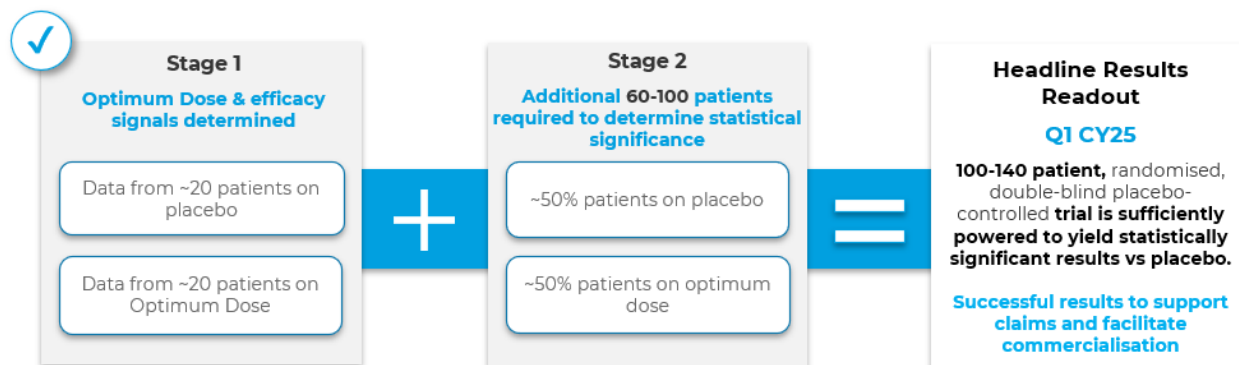
The target participant number is 60-100 for Stage 2 of the trial with 71 now confirmed as participating, and the Company anticipated this target number would be met before the end of Q4 CY2024 with the Headline Results readout anticipated in Q1 CY2025.

Participants are 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 both Stages of the trial will form the basis of the final analysis. This will result in a total of over 100 trial participants. The trial is designed to be sufficiently powered to deliver statistically significant results versus placebo, and final patient number considerations are currently being assessed.



GaRP-IBS Clinical Trial Design



Commencement of anti-obesity project

The anti-obesity project has been designed to develop an oral medication to assist weight reduction and sustaining weight control in conjunction with other contemporary treatments and approaches. The Company is allocating approximately \$250,000 to proof-of-concept studies for the anti-obesity project. The planned *in-vivo* pre-clinical experiments are in the final stages of preparation for ethics submission and, once the appropriate approvals are in place, these studies are anticipated to take approximately 6 months through to completion.

Ongoing Corporate Activities

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 both the desired evidence-based claim to differentiate GaRP as an IBS treatment and, a more valuable foundation to engage with global 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. The indications for the GaRP product are potentially much broader than IBS alone in GIT health and validation of the mechanism of action of the product for other conditions is a Company objective following the GaRP-IBS trial.

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, even with the commencement of the anti-obesity project.

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



Summary Q2 FY2025 cashflows

The Company's cash at the end of the quarter was \$1.052 million (31st September 2024: \$0.923 million). Net cash received from operating and financing activities during the quarter was \$0.128 million, compared to a \$0.06 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 \$81,000 which includes directors' fees and superannuation.

Anatara completed a successful capital raising of A\$0.75m in May 2024, reflecting strong support from existing institutional and sophisticated investors, with the issue price of \$0.05 being a discount of over 10% to the 30-day VWAP as at close of trade the day before raise.

An SPP on the same terms raised a further \$274,500.00. This was intended to give existing shareholders an opportunity to participate in the capital raise and was announced on 15th November 2024 with a closing date of the 18th of December 2024. Anatara Executive Chair Dr. David Brookes commented, at the time: *'The pleasing response to the SPP, combined with the Placement, means Stage 2 of the IBS trial and the new anti-obesity project are now funded beyond milestones that are important inflection points. On behalf of the Company, we thank those that participated in the capital raise for their ongoing support.'*

Other Corporate Activities

The Company announced the retirement of Company Secretary Mr. Stephen Denaro on the 29th of November 2024 with the appointment of Mr. Jonathan Lindh into that position. Jon Lindh is an experienced Lawyer and Company Secretary who currently serves as company secretary on a number of other listed and unlisted companies.

The Company's AGM was held on the 14th of November 2024 in Adelaide as hybrid meeting with in person and virtual attendance.

An investor webinar and Q&A was conducted virtually on the 2nd of December 2024 and was well attended by institutional, broker and retail participants.

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

Benzinga: <https://www.benzinga.com/content/42713459/exclusive-interview-with-dr-david-brookes-anatara-lifesciences-asx-anr>



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 **Gastrointestinal ReProgramming** 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")

31 December 2024

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (.....months) \$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers	-	-
1.2 Payments for		
(a) research and development	(560)	(823)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	(50)	(102)
(d) leased assets	-	-
(e) staff costs	(202)	(378)
(f) administration and corporate costs	(73)	(299)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	2	4
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	627
1.8 Other (provide details if material)	49	78
1.9 Net cash from / (used in) operating activities	(833)	(893)
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)
(e) intellectual property	-	-
(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (.....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)

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	1,025	1,095
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	(63)	(82)
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	961	1,012

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	923	982
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(833)	(893)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	(50)

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (.....months) \$A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	961	1,012
4.5	Effect of movement in exchange rates on cash held	1	1
4.6	Cash and cash equivalents at end of period	1,052	1,052

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	1,052	873
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)	1,052	923

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	81
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>		

7.	Financing facilities <i>Note: the term "facility" includes all forms of financing arrangements available to the entity. 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)	(833)
8.2	Cash and cash equivalents at quarter end (item 4.6)	1,052
8.3	Unused finance facilities available at quarter end (item 7.5)	0
8.4	Total available funding (item 8.2 + item 8.3)	1,052
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	1.26
	<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: Yes, given the Company is involved in the development and commercialisation of gastrointestinal health products and not currently generating revenue. The Company also notes that the trial R&D expenditure for the last Quarter is anticipated to be at its highest level.	
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: No, not in the immediate term. The Company has ongoing corporate and business development activities that are likely to be supportive of ongoing operations. The Company has been able to demonstrate a record of securing funds when required and is confident it will be able to continue to do so. The Company also has ongoing R&D tax rebate accrual.	

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: Yes, the Company believes that it will be able to continue its current operations and business objectives for the reasons outlined in 8.6.1 and 8.6.2.

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.

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: 15/01/2025

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.