

ASX Release

Anatara Lifesciences 4C & Q3 FY25 Activities Report

Highlights for the Quarter ending March 2025

- Company announced on the 20th February 2025 that Stage 2 enrolment number in the GaRP-IBS ("Irritable Bowel Syndrome") trial confirmed as 71 Intent-To-Treat participants with the trial remaining in "pause" status during an initial analysis.
- On the 10th March 2025, the Company's guidance for the GaRP-IBS trial, following a preliminary review of non-finalised data of Stage 2, was that the primary efficacy endpoint for IBS-SSS reduction versus placebo would be unlikely to be met. There were no apparent safety concerns and a number of secondary endpoints were also to be included in the headline result analysis .
- The planned *in-vivo* pre-clinical mice experiments for the Company's Anti-obesity Project received ethics approval in February and the proof-of-concept studies commenced during the Quarter with an agreement with the University of Newcastle.
- Subsequent to the March Quarter, the headline results analysis for the Phase II GaRP-IBS (Irritable Bowel Syndrome) trial on completion of Stage 2 were announced on 17th April 2025 with the following results:
 - headline results analysis confirmed no safety concerns and that the primary endpoint for efficacy of a reduction in IBS-SSS versus placebo was not met;
 - The secondary endpoint of improvement in anxiety scores reached statistical significance (P-value 0.034, Week 8) with depression scores remaining stable (within normal range);
 - IBS-SSS ("SSS" Symptom Scoring System) experienced consistent and sustained improvement, with reduction of more than 40% observed, but did not reach statistical significance when compared to placebo. Further, the secondary endpoint of a 20% or more reduction (improvement) in IBS-SSS compared to baseline in the trial cohort on the GaRP product was clearly achieved;
 - Pleasingly, secondary endpoint of IBS-Adequate Relief highly significant at 10 weeks with a P-value 0.004, indicating self-assessment of participants as "responders" outweighed "non-responders" versus placebo was statistically significant.
- The summarisation of the GaRP project pre-clinical and clinical work remains a priority to enhance the understanding of the commercial possibilities for the GaRP product in gastrointestinal health.



ADELAIDE, 30 April 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 provided on the Company’s GaRP-IBS trial progress and the analysis, the anti-obesity project and other current activities. Subsequent to the end of Q3CY25, the mixed GaRP-IBS trial headline analysis has resulted in a review of the Company’s direction and immediate operational needs.

Stage 2 of Anatara’s GaRP-IBS (Irritable Bowel Syndrome) Phase II trial

On 28 January 2025, the Company announced the receipt of the certification of the grant of a standard patent for the GaRP product under the invention title of “Gastrointestinal Health Composition”. The patent numbered 2020364192 was granted by the Commissioner of Patents for the Australian Patent Office and has a term of 20 years from 9 October 2020 (therefore the expiry date is 9 October 2040).

This followed the grant of a European patent from the European Patent Office (EPO) for the title and documents relating to its Gastrointestinal ReProgramming product (known as “GaRP”). That decision from the EPO took effect from the publication of the grant in the European Patent Bulletin 24/38 on the 18th September 2024.

On 20 February 2025, the Company announced that the recruitment for the GaRP-IBS trial had been paused since mid-December 2024 and those last enrolled and participating had entered the mandatory final 2 week follow up period after being randomised to receive either placebo or the GaRP product. This was consistent with previous guidance and the usual processes of data lock through to analysis.

On 14 January 2025, the Company announced the Stage 2 enrolment number in the GaRP-IBS trial being confirmed as 71 Intent-To-Treat participants. The trial participant numbers were in line with Company expectations and the usual activities to finalise Stage 2 occurring at the trial sites.

On 10 March 2025, the Company provided guidance on its preliminary analysis of the GaRP-IBS trial that the primary endpoint, a statistically significant improvement (meaning reduction) in IBS-SSS when compared to placebo, was unlikely to be achieved. The Company also advised that the secondary endpoint of >20% improvement in IBS-SSS from baseline appears highly likely to be achieved.

Following the end of the Quarter on 17 April 2025, the Company announced the completion of Stage 2 GaRP-IBS (Irritable Bowel Syndrome) Phase II trial with the headline results analysis confirming no safety concerns and that the primary endpoint for efficacy of a reduction in IBS-SSS versus placebo was not met, despite a consistent and meaningful response being observed during the trial.

The secondary endpoint of improvement in anxiety scores reached statistical significance (P-value 0.034, Week 8), which influenced the significance of the overall HADS score (P-value 0.025 at Week 8), with depression scores remaining stable (within normal range). “HADS” being the commonly used Hospital Anxiety Depression Scale.



The IBS-SSS (“SSS” Symptom Scoring System) experienced a consistent and sustained improvement, with a reduction of more than 40% observed in the trial, but this did not reach statistical significance when compared to placebo. Another secondary endpoint of a 20% or more reduction (improvement) in IBS-SSS compared to baseline in the cohort on the GaRP product was clearly achieved.

Pleasingly, the secondary endpoint of IBS-Adequate Relief was highly significant at 10 weeks with a P-value 0.004, indicating the self-assessment of participants as “responders” clearly outweighed “non-responders” versus placebo.

Anti-Obesity Project

On 20th February 2025, the Company announced that the planned *in-vivo* pre-clinical mice experiments had been approved following ethics submission and were underway following agreements with the University of Newcastle. The studies are anticipated to take approximately 6-9 months through to completion, depending on the extent to which weight control is sustained in the animal model.

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.

Specifically, the product is being developed with the target of assisting the maintenance of weight loss and limiting rebound weight gain following cessation of contemporary weight loss medications.

While the Company needs to protect the project at this early stage, the mechanism of action involves the stimulation of endogenous GLP-1. The Company will assess several compounds of interest (that have been sourced/manufactured) in the pre-clinical studies to determine the best candidate/s going forward. The candidate compounds selected have been shown to target the same biochemical mechanism that is the focus of the Proof-of-Concept (POC). The dosage regimes have been predicted from published pre-clinical and clinical studies.

The Company has allocated more than \$250,000 to the POC studies for the anti-obesity project and will determine further steps as the results of these initial studies are assessed.

Summary Q3 FY2025 cashflows

The Company’s cash at the end of the quarter was \$0.393 million (31st December 2024: \$1.052 million). Net cash outflows from operating and financing activities during the quarter was \$0.660 million, compared to the net inflow from operating and financing activities of \$0.128 million in the previous quarter.

The aggregate payments to related parties and their associates during the quarter totalled \$68,000 which includes directors’ fees and superannuation.

The Company notes that the cash position is stable and the accumulating R&D tax incentive rebate was approximately \$500k at the end of H1FY25.



Board Changes

The Company announced the resignation of Non-Executive Director Mr. Nicholas Haslam on the 28th of February 2025 with the appointment of Mr. Jonathan Lindh into that position in addition to his company secretarial role. Mr Lindh is an experienced Lawyer and Company Secretary who currently serves as company secretary on a number of other listed and unlisted companies.

Other Corporate Activities & Future Direction

While committed to the Anti-Obesity Project Proof of Concept studies, the Company has advised that it is assessing other opportunities and directions. The summarisation of the GaRP project pre-clinical and clinical work remains a priority to enhance the understanding of the commercial possibilities for the GaRP product in gastrointestinal health. The patent position for the GaRP project is current and remains protected. Furthermore, the Company is still investigating the potential for broad indications of the GaRP product, including in the management of a healthy gut-brain axis. However, manufacturing and the procurement of ingredient components are not a priority.

Given the outcome of the results of the GaRP Stage 2 of Anatara's GaRP-IBS (Irritable Bowel Syndrome) Phase II trial, the Company has maintained only essential roles around the retracted activities until the Company's direction is further defined. Mr. John Michailidis will be in a non-executive director role only from the late April 2025, as part of a planned transition to retire the COO role to coincide with Company inflection points. Mr. Simon Erskine will also reduce his workload next month to 0.8 FTE as CDO for the foreseeable future. These operational initiatives accompany a general reduction in contracted services to the Company that are not immediately relevant following the mixed GaRP-IBS trial outcome which missed significance for the primary efficacy endpoint.

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 **Re**Programming 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 March 2025

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (9 months) \$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers	-	-
1.2 Payments for		
(a) research and development	(381)	(1,204)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	(51)	(153)
(d) leased assets	-	-
(e) staff costs	(172)	(550)
(f) administration and corporate costs	(104)	(404)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	2	7
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)	58	135
1.9 Net cash from / (used in) operating activities	(649)	(1,542)
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 (9 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)	-	1,095
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	(10)	(92)
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	(10)	1,003

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	1,052	982
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(649)	(1,542)
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 (9 months) \$A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(10)	1,003
4.5	Effect of movement in exchange rates on cash held	(1)	-
4.6	Cash and cash equivalents at end of period	393	393

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	393	1,052
5.2	Call deposits	-	-
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)	393	1,052

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	68
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.</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)	(649)
8.2	Cash and cash equivalents at quarter end (item 4.6)	393
8.3	Unused finance facilities available at quarter end (item 7.5)	0
8.4	Total available funding (item 8.2 + item 8.3)	393
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	0.61
<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, the Company is a developer of health products and is not currently generating revenue. Expenditure is anticipated to be lower in Q4 due to reduced human trial activity and cost saving measures.	
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: Yes, the Company has ongoing corporate activities that will determine cash needs and availability . The Company has ensured ready access to a significant R&D tax rebate accrual. The Company has demonstrated a record of securing funds when required and remains confident of being able to do so, if necessary.	

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, 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: 30 April 2025

Authorised by: By the Board
(Name of body or officer authorising release – see note 4)

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.