

**ASX Release** 

# Anatara Lifesciences 4C & Q4 FY24 Activities Report

# **Highlights**

- Recruitment is proceeding well for the second stage of Anatara's pivotal GaRP-IBS (Irritable Bowel Syndrome) trial with extension further into Q3 CY2024. Headline Results readout anticipated late Q4 CY2024.
- High levels of interest are still being shown at all 5 sites in Melbourne, Sydney and Brisbane with suitable numbers of potentially eligible candidates identified and being encouraged into the formal enrolment process.
- 18 participants having already been enrolled into Stage 2 of the trial and a further approximately 20 are currently in screening to determine suitability for enrolment.
- Completed a successful capital raising via a A\$1.0m Placement, 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 5<sup>th</sup> July 2024.

ADELAIDE, 30 July 2024: Anatara Lifesciences (ASX: ANR or "the Company"), a developer of evidence-based solutions for gastrointestinal diseases in humans, is pleased to report that recruitment for the second stage of Anatara's pivotal GaRP-IBS (Irritable Bowel Syndrome) trial is proceeding well and remains on budget. There has been an extension to the recruitment timeline, with the expectation that this will continue through August.

Stage 2 of the GaRP-IBS trial is the planned extension that follows the successful completion of Stage 1 of the Phase II trial 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*).





There have been high levels of interest shown at all 5 sites situated in Melbourne, Sydney and Brisbane with over 1,000 Expressions of Interest (EoI) to date. Following the trial protocol screening processes, consistent with Stage 1 of the trial, enrolments are at 18 participants in Stage 2 of the trial, some of whom have completed the treatment phase. A further group of approximately 20 participants are currently in screening to determine suitability to enter the trial and a much larger group of potential participants have been identified as eligible from the initial questionnaires to be followed up for screening.

Anatara Executive Chair, Dr. David Brookes commented: "The Company is very focused on the completion of the GaRP-IBS trial and having a headline readout by the end of this calendar year. We believe this is achievable and have contingencies in place should any aspect of the recruitment process need bolstering or support. The recent push by various media modalities has re-invigorated the momentum at the expressions of interest level which all the sites are working to convert through to enrolment. While taking this opportunity to thank the trial sites, we would particularly like to express our appreciation to the current and future participants for their self-less commitment of involvement in a trial for a potential breakthrough IBS treatment."

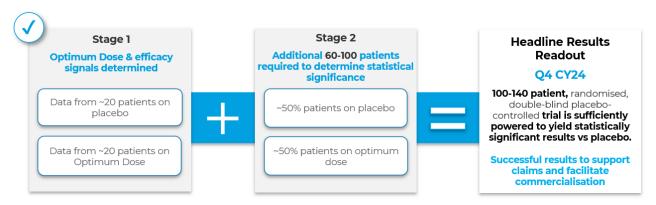
The target participant number is 60-100 for Stage 2 of the Trial and the Company anticipates this target number will be met before the end of Q3 CY2024 with Headline Results readout anticipated late Q4 CY2024, in line with previous guidance.

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

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 initiatives**

The results to-date have signalled a promising new era in the quest to alleviate the burdens of IBS and related disorders. Confirmation of these results 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 complementary medicines. 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. There are also ongoing discussions for potential uses of Anatara's established products and know-how for animal health.

Dr. Micheal West, Chief Scientific Officer (CSO), represented Anatara at several conferences and partnering meetings during the quarter, including in Europe. A number of these discussions remain ongoing. Dr West also met with counterparties and regulatory advisors to discuss GaRP manufacturing and GMP. The Company is securing a supply chain of materials for commercial readiness of the GaRP product.

## **Summary Q4 FY2024 cashflows**

The Company's cash at the end of the quarter was \$0.982 million (30<sup>th</sup> March 2024: \$0.645 million). Net cash outflow from operating activities during the quarter was \$0.856 million, compared to a \$0.384 million cash outflow from operating activities in the previous quarter. This is primarily related to the initiation of Stage 2 of the IBS Clinical Trial.

The aggregate payments to related parties and their associates during the quarter totalled \$84,000, which includes directors' fees and superannuation.

Anatara completed a successful capital raising of A\$1.0m, 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 5<sup>th</sup> July 2024.

# Subsequent events

As announced on the 5<sup>th</sup> July 2024, the placement participation by Chair David Brookes (\$60,000) and COO, John Michailidis (\$10,000) was approved by shareholders at the EGM. This additional \$70,000 in cash will be reflected in the upcoming quarter's 4C.





## **Other Corporate Activities**

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

Australian Business Journal: Understanding the Impact of IBS in Australia: The Implications of Anatara Lifesciences' GaRP-IBS Trial.

https://theabj.com.au/2024/06/15/understanding-the-impact-of-ibs-in-australia-the-implications-of-anatara-lifesciences-garp-ibs-trial/

The Tech Bullion: Anatara Lifesciences' GaRP-IBS Trial and the Battle Against IBS in Australia

https://techbullion.com/anatara-lifesciences-garp-ibs-trial-and-the-battle-against-ibs-in-australia/

The Auspreneur: Examining the Impact of IBS in Australia and Anatara Lifesciences' GaRP IBS Trial

https://auspreneur.com.au/examining-the-impact-of-ibs-in-australia-and-anatara-lifesciences-garp-ibs-trial/

Yahoo Finance News: Shining a Spotlight on IBS: Anatara Lifesciences Makes Strides in Phase II Trial during IBS Awareness Month

https://finance.yahoo.com/news/shining-spotlight-ibs-anatara-lifesciences-163000049.html

#### **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.

For more information please contact:

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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.

#### Disclaimer

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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 Quarter ended ("current quarter")

41 145 239 872 30 June 2024

Con	solidated statement of cash flows	Current quarter \$A'000	Year to date (12 months) \$A'000
1.	Cash flows from operating activities		
1.1	Receipts from customers	-	-
1.2	Payments for		
	(a) research and development	(266)	(941)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	(28)	(154)
	(d) leased assets	-	-
	(e) staff costs	(202)	(682)
	(f) administration and corporate costs	(92)	(597)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	2	8
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	942
1.8	Other (provide details if material)	16	176
1.9	Net cash from / (used in) operating activities	(569)	(1,247)

2.	Cas	sh flows from investing activities	
2.1	Pay	ments to acquire or for:	
	(a)	entities	-
	(b)	businesses	-
	(c)	property, plant and equipment	-
	(d)	investments	-
	(e)	intellectual property	-
	(f)	other non-current assets	-

ASX Listing Rules Appendix 4C (17/07/20)

Con	solidated statement of cash flows	Current quarter \$A'000	Year to date (12 months) \$A'000
2.2	Proceeds from disposal of:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(d) investments	50	50
	(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)	930	1,985
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	(74)	(157)
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	856	1,828

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	645	351
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(569)	(1,247)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	50	50

Con	solidated statement of cash flows	Current quarter \$A'000	Year to date (12 months) \$A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(856)	1,828
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	Cash and cash equivalents at end of period	982	982

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	932	645
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)	982	645

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	84
6.2	Aggregate amount of payments to related parties and their associates included in item 2	
	if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must including taking for such payments	le a description of, and an

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

7.	Financing facilities  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.	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.		itional financing

8.	Estimated cash available for future operating activities	\$A'000
8.1	Net cash from / (used in) operating activities (item 1.9)	(570)
8.2	Cash and cash equivalents at quarter end (item 4.6)	982
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	982
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	1.72
	Note: if the entity has reported positive net operating cash flows in item 1.9, answer item figure for the estimated quarters of funding available must be included in item 8.5.	8.5 as "N/A". Otherwise, a

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: Ye			

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, R&D tax rebate anticipated in this Quarter following lodgement of return. Also, there are ongoing corporate and business development activities that are likely to be successful and supportive of Company's initiatives and projects.

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, please see 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 July 2024		
	Shirt Des		
Authorised by:	(David Brookes on behalf of 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.
- 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.