ASX Release



Anatara Lifesciences 4C & Q1 FY23 Activities Report

Q1FY23 Highlights

- Revised protocol for Irritable Bowel Syndrome (IBS) trial of "GaRP" 90 patient trial successfully implemented and enrolment on track for interim read-out of results anticipated to be no later than in Q2CY2023
- 3FDC psychological functioning trial with CSIRO halted; no safety concerns
- Subsequent event post quarter end of \$865,000 Placement and launch of \$832,000 Entitlement Offer to existing shareholders
- R&D Tax Refund of \$480,000 received
- Funds will be utilised to reach interim read-out on the GaRP-IBS trial, for future project acquisitions and to strengthen Anatara's balance sheet
- Result of recent trial of ANR-pf(poultry) with major Australian producer, although inconclusive, points to potential prevention study. Discussions remain ongoing

MELBOURNE, 28 October 2022: Anatara Lifesciences (ASX: ANR or "the Company"), a developer of evidence-based solutions for gastrointestinal diseases in humans and animals, is pleased to provide a quarterly summary of activities for the quarter ending September 30th 2022 along with the Company's Appendix 4C cash flow report.

GaRP - Irritable Bowel Syndrome (IBS) - Trial Update

The new broader "GaRP" (Gastrointestinal Re-Programming complementary medicine) trial criteria of IBS modified to exclude only the constipation subset and the focus on screen failure inconsistencies that became apparent as the trial progressed has increased interest in participation with both new and some previous participants. This is also expected to result in stronger conversion from interest to enrolment, and the Company has been closely monitoring the ongoing momentum of both patient interest and recruitment into trial participation. There are now improved enrolment rates towards the required 90 patients to complete Stage 1 for the interim readout. Following the broadening of the GaRP trial criteria, the Company is confident that the findings of the continuing review process will allow ongoing momentum with enrolment. The current recruitment rate and reinforcement will likely result in the interim analysis becoming available in 2QCY2023

The Royal Melbourne Hospital is the latest site that has been approved and onboarded as a recruitment site for the IBS trial. The recent initiation will assist the GaRP trial progress with potential participants already in screening. Additional sites and services to make participation in the trial easier are being considered internally with a view to enhancing recruitment and compliance.

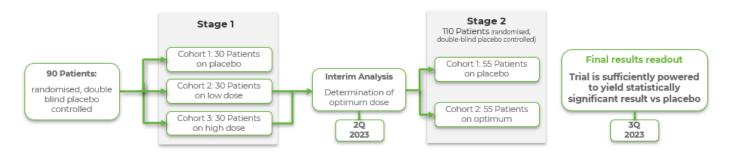
Anatara Lifesciences Limited
Registered Office
Level 3, 62 Lygon Street, Carlton South, VIC, 3053, Australia
Administration and R&D
Suite 101, 55 Flemington Rd, North Melbourne, VIC 3051, Australia
Email info@anatara.com | Website anataralifesciences.com



The GaRP IBS trial is powered to deliver results that will validate support claims. If successful, the high prevalence of digestive disorders requiring relief from both symptoms and the disease process, including irritable bowel syndrome (IBS), present a significant market opportunity for Anatara.

The commercial opportunity for non-prescription products for gastrointestinal disorders and IBS is US\$8 billion in the US.¹

Clinical Trial Design



3FDC - Psychological functioning trial

The psychological functioning study being conducted by the CSIRO using 3FDC was in the process of recruiting ~100 patients with mild to moderate levels of depression, anxiety, or stress symptoms indicated by the Depression, Anxiety and Stress Scale (DASS-21).

During review of all Anatara clinical trials, it became apparent that the sample size required to detect a signal in this study may be higher than initially proposed to reach a reliable outcome. Whilst it is common for anxiety and depression trials to have high placebo responses, the Board of Anatara have elected to halt the study on the balance of outcome probability rather than considering a commitment to significant future costs.

Importantly, there were no concerns around safety or tolerance with 3FDC to date, and none are anticipated. The GaRP complementary medicine includes a subset of 3 components formulated for release in the lower large intestinal tract which have been labelled "3FDC".

There remains a strong rationale regarding the influence on the "gut-brain" axis and the homeostasis of the microbiome and the Company notes the Hospital Anxiety and Depression Scale (HADS) and Quality of Life (QOL) assessments within the questionnaire of the GaRP clinical trial will allow for preliminary analyses of the influence of the total GaRP components, in participants with gastrointestinal symptoms, on depression and anxiety.

Animal Health Programs

The results from the most recent trial of ANR-pf (poultry) with a major Australian chicken producer were inconclusive, however, discussion pointed to potential prevention studies as the route forward. Discussions remain ongoing. These considerations have been agreed for ongoing discussion in the near future. The need to address antimicrobial resistance across animal production remains a strong focus in the industry.

 $^{^1\} https://www.grandviewresearch.com/press-release/global-brain-health-supplements-market$

As previously advised in ASX announcements, and based on previous trials, the Company believes there is a significant commercial opportunity, or otherwise, if ANR-pf(poultry) delivered in water provides a benefit and has the potential for use in other species. In particular, the pig industry feed and product suppliers have indicated a strong preference for a similar water product rather than Anatara's BONIFF as a weaner feed, which requires manpower to mix in feeds. The Company is of the view that it is likely to be able to adapt the learning from BONIFF's development and is encouraged by the potential to be a replacement for the Zinc Oxide commercial preparations that are now banned in the EU.

Ongoing corporate initiatives

In preparation for the GaRP trial results, Anatara is engaging with global pharma companies interested in expanding their portfolio of complementary medicines. The trial is garnering interest from global leaders in the GI field due to the strong evidence-based design of the GaRP trial.

The Company is also actively assessing other opportunities in the healthcare space.

Summary Q4 FY2022 cashflows

The Company's cash at the end of the quarter was \$0.827 million (30th June 2022: \$1.12 million).

Proforma cash position as of 28 October 2022 is approximately \$ 1.5 million which includes proceeds from the completed placement component of the recent capital raise (pre-costs) .Net cash used in operating activities during the quarter was \$0.287 million down from \$0.568 million from the previous quarter.

An R&D tax incentive of \$0.48 million was received in late September 2022.

Aggregate payments to related parties and their associates during the quarter \$68,000 which includes directors' fees and superannuation.

Subsequent Activities - Placement and Entitlement Offer

The Company announced (ASX Release: 21 Oct 2022) it had received firm commitments for approximately \$0.865m in a successful Placement and launched a 1-for-3 Entitlement Offer to raise \$0.832m.

The capital raise will be used to reach interim read-out in the form of a futility analysis on Stage 1 of the GaRP-IBS (Irritable Bowel Syndrome) trial involving 90 participants, with enrolment anticipated to be completed in Q1CY2023 and the analysis no later than Q2CY2023. Funds will also be used for future project acquisitions and to strengthen Anatara's balance sheet.

Taylor Collison Limited acted as Lead Manager and Candour Advisory Pty Ltd acted as Advisor to the Company.

For more information please contact:

Dr. David Brookes
Chair, Anatara Lifesciences Ltd
+61 (0) 411 712 579
dbrookes@anatara.com

Dirk van Dissel
Candour Advisory – Investor Relations
+61 (0) 408 326 367
dirk@candouradvisory.com.au

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 September 2022

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	(186)	(186)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	(46)	(46)
	(d) leased assets	(2)	(2)
	(e) staff costs	(252)	(252)
	(f) administration and corporate costs	(298)	(298)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	-	-
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	480	480
1.8	Other (provide details if material)	17	17
1.9	Net cash from / (used in) operating activities	(287)	(287)

<u>.</u>	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	-

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

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (3 months) \$A'000
	(f) other non-current assets	-	-
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	-	-

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	-
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	-	-
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)	(6)	(6)
3.10	Net cash from / (used in) financing activities	(6)	(6)

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	1,120	1,120
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(287)	(287)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	-

Con	solidated 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)	(6)	(6)
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	Cash and cash equivalents at end of period	827	827

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	827	1,120
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)	827	1,120

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	-
	if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must includation for such payments	de 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 qu	arter end	
7.6	Include in the box below a description of each facility above, including the lender, interestate, 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)	(287)
8.2	Cash and cash equivalents at quarter end (item 4.6)	827
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	827
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	3
	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

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

8.6

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

- 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: 28 October 2022

Authorised by: The Board of Anatara Lifesciences Ltd

Notes

- 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.