ASX Release

Anatara Lifesciences Appendix 4C and Q2 FY22 Activities Report

The Appendix 4C and Q2 FY22 Activities Report replacement document contains one change only: the removal of the “DRAFT” watermark from the first page of Appendix 4C.

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Anatara Lifesciences Appendix 4C and Q2 FY22 Activities Report

Key highlights for Q2 FY22

- **Anatara is encouraged by continuing interest in the human trials by clinical researchers and potential commercialisation partners; The Company anticipates adding a new IBS-D clinical trial site in February 2022 and will continue to explore additional opportunities to complete the trials earlier than the revised guidance from trials coordinators**
- **Strengthened management team with appointments of Chief Development Officer Simon Erskine and Head of Business Development & Marketing Communications Michael Pryor**
- **Received $736,476 from the Australian Taxation Office under the Federal Government's Research and Development (R&D) tax incentive scheme**
- **Delays in human trials due to COVID-19 restrictions**
- **Irritable Bowel Syndrome - diarrhoea subtype(IBS-D); new Adelaide site to commence trial recruitment in mid-February; Interim report is now anticipated in August 2022 and final report in January 2023; additional augmentation of recruitment is being considered to address the delay**
- **3FDC trial is now anticipated to start mid-February; final report is now anticipated in late 2022**

MELBOURNE, 27 January 2022: Anatara Lifesciences (ASX: ANR), a developer of evidence-based solutions for gastrointestinal diseases in humans and animals , is pleased to provide this activities report for the quarter ending 31 December 2021 (Q2 FY22), along with the Company's Appendix 4C cash flow report.

Commenting on the quarter, CEO Steve Lydeamore said, "We were really pleased with the additions to our leadership team, with Michael Pryor joining as our Head of Business Development & Market Communications, and Simon Erskine joining as Chief Development Officer. Both Michael and Simon bring extensive industry experience, are highly regarded in their respective fields, and importantly, will assist us to accelerate our commercialisation and grow our gastrointestinal health technology portfolio.

"With the high prevalence of digestive disorders, including irritable bowel syndrome (IBS), and the burgeoning interest in the "gut-brain" axis globally, there are significant market opportunities in addressing these issues while improving individuals' quality of life. Despite some COVID-19 related delays, we are progressing GaRP human trials for irritable bowel syndrome (IBS-D; diarrhoea subtype) and 3FDC for psychological functioning.

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"We are anticipating that recruitment for both our human clinical trials for 3FDC and GaRP will take place from mid-February 2022 at the CSIRO site and other recruitment pathways for the GaRP trial are being continually reviewed and reinforced."

Anatara strengthens the team with new appointments

Michael Pryor and Simon Erskine were appointed to progress the Company's commercialisation activities in the gastrointestinal health space.

Mr Erskine joined as Chief Development Officer, with more than 10 years' experience working within the biotechnology, IVD (in vitro diagnostic) medical devices and molecular diagnostic industries. He has held numerous research and development roles including product and clinical development, regulatory affairs and quality assurance, and has successfully translated early-stage research into commercial products for the Australian, European, Canadian and US markets.

Mr Pryor's most recent role was Commercial Manager (ANZ) at MENARNI Group where he led a highly successful team, driving sales, market share and profit growth within the pharmacy channel. Mr Pryor has developed an intimate understanding of the Australian pharmacy channel and has worked across a wide range of therapeutic areas, including gut health.

The appointments of Michael and Simon will play a key role in expanding Anatara's position as an emerging leader in evidence-based gut health solutions.

Clinical trials update

IBS-D

The IBS-D study consists of two stages (Stage 1, Stage 2), with an interim analysis between stages. Stage 1 will assess the safety, tolerability and efficacy of two different strengths of GaRP against placebo in a 1:1:1 randomisation protocol. Following interim analysis, one dose will be selected, and the remaining participants recruited in a 1:1 randomisation protocol. Of the 200 planned participants, at least 90 will enrol in stage 1, and 110 participants will enrol in stage 2. For each participant in each stage, the study will last for 12 weeks, including 8 weeks of treatment, preceded by a 2-week screening/baseline period and followed by a 2-week washout period.

Anatara continues to take actions to recover trial participants in the IBS-D trial. Potential trial participants were previously excluded as their IBS Symptom Severity Scores (IBS-SSS) were marginally higher than the trial inclusion criteria, however, Anatara applied for, and received, ethics approval to modify the criteria which has now expanded the pool of potential patients.

Recruitment has commenced, but has been significantly hindered by the impact of Omicron, with Anatara adding an additional site in Adelaide for the IBS-D trial but recruitment has been delayed into February 2022 . This new site will target recruitment of up to 50 participants. The Company has also engaged Evrima, a specialist in patient identification and recruitment. Evrima will support Anatara's IBS-D trial by both direct-to-patient and direct-to-clinician channels. Direct-to-patient will increase community awareness via social media, digital marketing campaigns and radio advertising. Direct-to-clinician will generate awareness within the GP community, as well as through the use of their proprietary software to identify potentially eligible patients via electronic health records in Australia.

Psychological functioning

Anatara's 3FDC is several of the components of the GaRP (Gastrointestinal reprogramming) complementary medicine. The 3FDC components are coated for targeted release predominately beyond the small intestine to allow delivery and influence in the large intestine. The 3FDC components are anticipated to have direct and indirect effects including assisting the homeostasis of a healthy microbiome. The delivery of these components and the microbiome influences are considered important for gut-brain axis balance, hence the 3FDC components have been selected to explore their effect on depression, anxiety and stress symptoms in otherwise healthy individuals.

This randomised, double-blinded, placebo-controlled study into the effects of 3FDC in adults with moderate anxiety, stress or depression will be conducted at CSIRO's Nutrition and Health Research Clinic in Adelaide. Approximately 100 participants will be randomised in a 1:1 manner for treatment with 3FDC or a placebo, dosed twice a day for 6 weeks.

Commenting on progress made towards the human clinical studies, CEO Steve Lydeamore said, "While we anticipated a pause in recruiting over the Christmas break, as well as the potential impact of diet and lifestyle during that period, investigational product was not received from India in time to commence recruitment for the psychological functioning trial prior to Christmas.

"Following this, the recent escalation in COVID-19 cases means that IBS-D recruitment at the new Adelaide site will not commence until the end of February due to COVID-19 restrictions at CSIRO's Adelaide facility. The CSIRO advised of the need to push back the timeframes to allow appropriate management of staff and resources during the Omicron COVID-19 uncertainty. For the same reason the start date of the 3FDC trial is delayed until the end of February.

"There is a major unmet need and significant market opportunity for an evidence-based complementary medicine for IBS. Anatara's GaRP has demonstrated that it has the potential to manage the devastating symptoms experienced by IBD and IBS patients, by addressing processes that contribute to the pathophysiology of these chronic bowel conditions. Although we're experiencing temporary delays due to COVID-19, we remain highly optimistic that our technology has the potential to make a substantial positive impact to gastrointestinal health and we look forward to the resumption of recruitment activities next month."

Summary of Q2 FY22 cashflows

The Company's cash plus term deposits at the end of the quarter stood at $2.56 million (30 September 2021: $2.53 million), which comprised cash at bank of $1.56 million and $1.00 million in term deposits. During December the Company received an R&D Tax Incentive of $736k.

Net cash inflow during the quarter was $0.05 million. Staff, Admin and Corporate cash outflow of $0.59 million was 2.4% higher than the prior quarter.

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

Authorised by: The Board of Anatara Lifesciences Ltd

For more information please contact:

General inquiries	
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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.

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	31 December 2021

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (6 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	-	-
1.2	Payments for		
	(a) research and development	(117)	(468)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	(26)	(32)
	(d) leased assets	-	(5)
	(e) staff costs	(344)	(638)
	(f) administration and corporate costs	(242)	(520)
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	736	736
1.8	Other (provide details if material)	40	78
1.9	**Net cash from / (used in) operating activities**	**49**	**(845)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(7)	(7)
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (6 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**	**(7)**	**(7)**

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)	(6)
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)	(7)
3.10	**Net cash from / (used in) financing activities**	**(9)**	**(13)**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	2,525	3,423
4.2	Net cash from / (used in) operating activities (item 1.9 above)	49	(845)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(7)	(7)

Consolidated statement of cash flows		Current quarter $A'000	Year to date (6 months) $A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(9)	(13)
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash and cash equivalents at end of period**	**2,558**	**2,558**

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	1,558	1,025
5.2	Call deposits	1,000	1,500
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)**	**2,558**	**2,525**

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	-

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.

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.	

8.	**Estimated cash available for future operating activities**	**$A'000**
8.1	Net cash from / (used in) operating activities (item 1.9)	49
8.2	Cash and cash equivalents at quarter end (item 4.6)	2,558
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	2,558
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	N/A

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.

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

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: 27 January 2022

Authorised by: The Board of Anatara Lifesciences Ltd

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.