

Anatara Lifesciences progressing towards its first human clinical studies; discussions with potential partners ongoing

Q3 FY21 Activities Report

Key highlights for Q3 FY21

- Human Research Ethics Committee approval to undertake a clinical trial of Anatara's Gastrointestinal Re-Programming (GaRP) complementary medicine for the condition of irritable bowel syndrome (IBS)
 - Recruitment for trial to commence in May 2021 for patients with "IBS-D" (subtype with diarrhoea)
 - Reinforcement of Anatara's commitment to an evidence-based approach to gastrointestinal health needs
- Post-balance date developments include Australian patent grant for Anatara's animal health product, Detach, and ethics approval to start Psychological Functioning Trial in humans
- Discussions with potential GaRP partners ongoing
- Successful completion of poultry challenge trial the commercial significance is being evaluated by animal feed companies and poultry producers
- Research & Development tax incentive of \$888k received; Company well funded with cash plus term deposits of \$4.0 million at quarter end

MELBOURNE, 27 April 2021: Anatara Lifesciences (ASX: ANR), a developer of non-antibiotic oral solutions for gastrointestinal diseases in animals and humans, is pleased to provide this activities report for the quarter ending 31 March 2021, along with the Company's Appendix 4C cash flow report.

Commenting on the quarter, CEO Steve Lydeamore said, "Anatara is pleased to have successfully progressed two key milestones during the period – a successful trial for Anatara's proprietary enriched formulation for poultry in water, and ethics approval to start the human IBS trial.

"Anatara now has approval to commence two separate human trials for its Gastrointestinal Re-Programming complementary medicine (GaRP), and there appears to be a wider appreciation of the Company's human health initiatives and the potential to improve overall human wellbeing with a market differentiating focus on *evidence based* complementary medicine.

"We also remain very encouraged by the progress we are making in the animal health areas, particularly in targeting the need for feed products for growth enhancement that avoid the use of antibiotics or zinc oxide."

Anatara Lifesciences Limited
Registered Office
Level 3, 62 Lygon Street, Carlton South, VIC, 3053, Australia
Administration and R&D
343 Royal Parade, Parkville, Melbourne, VIC 3052, Australia
Email info@anatara.com | Website anataralifesciences.com

Successful completion of poultry challenge trial

In February Anatara announced the successful completion of the poultry challenge trial "Efficacy of ANR-pf on the performance of broilers subject to subclinical and necrotic enteritis challenges". ANR-pf is Anatara's proprietary enriched formulation for poultry in water, designed to allow the full delivery of key additives in a quick and flexible dosing method on-farm even when stock illness is a concern.

Necrotic enteritis (NE) in broiler chickens is a common disease found in all poultry-growing areas of the world which can be controlled by antibiotics. However, with a European ban and worldwide phasing-out of in-feed antibiotics, the focus on alternative strategies has increased to secure chicken health, representing an attractive opportunity for Anatara's formulation.

The commercial significance of the trial is currently being evaluated by animal feed companies and poultry producers.

Ethics approval to start IBS Trial

In February Anatara announced that it had received Human Research Ethics Committee approval to undertake a clinical trial of its Gastrointestinal Re-Programming complementary medicine (GaRP) of participants with irritable bowel syndrome – diarrhoea subtype (IBS-D).

Anatara has now completed the necessary pre-clinical safety and efficacy testing of GaRP required to commence human clinical trials. Recruitment for the trial is planned to begin in May.

IBS is the most commonly diagnosed gastrointestinal condition and a significant cost burden on health care, yet there are limited pharmacological treatment options and symptoms are not well controlled.

Anatara has strong pre-clinical data to support use in IBS, and the human trials are the key next step to moving closer to commercialisation, and tapping into the US\$8+ billion gastrointestinal supplements and over-the-counter digestive remedies market¹.

Post-balance date developments

Australian patent grant for Detach®

In April Anatara announced the grant of patent number AU2019204496 entitled "Anti-diarrhea formulation which avoids antimicrobial resistance".

Anatara's animal heath product, Detach®, uses the patent as a non-antibiotic approach to aid in the control of diarrheal disease (known as scour), developed using bromelain, an extract from pineapple stems.

The patent claims cover an oral formulation of bromelain effective to treat and prevent diarrhea caused by pathogenic microbes. This formulation does not kill pathogenic microbes, and thus does not facilitate the proliferation of anti-microbial resistant organisms. The patent is fully owned by Anatara and will expire on 24 August 2038.

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¹ Mintel's 2018 Digestive Health U.S. – July, 16; Nutrition Business Journal (NBJ)

The patent provides the pathway for Anatara to further pursue commercialisation opportunities for Detach®.

Ethics approval to start Psychological Functioning Trial in adults

In April Anatara advised that it had received Human Research Ethics Committee approval to undertake a clinical trial on the effects of 3FDC dietary supplementation on psychological functioning in an adult population, in collaboration with CSIRO.

3FDC is one of the components of Anatara's GaRP dietary supplement that exerts its effects on the microbiome in the large intestine. Since restoration of a healthy microbiome is considered important for gut-brain axis balance, the 3FDC components have been selected to explore their effect on depression, anxiety and stress symptoms in otherwise healthy individuals.

The CSIRO team will develop the work guidelines and initiate recruitment with the aim of dosing the first participants in the third quarter of calendar year 2021. Recruitment is anticipated to take 6 months after which data analysis will be undertaken prior to final reporting.

Summary of Q3 FY21 cashflows

The Company's cash plus term deposits at the end of the quarter stood at \$3.96 million (31 December 2020: \$3.68 million), which comprised cash at bank of \$1.46 million and \$2.5 million in term deposits.

A positive net cash inflow during the quarter of \$0.32 million was due to the R&D Tax Incentive of \$0.89 million received, and lower R&D cash outflow due to timing of expenditure on the GaRP clinical trial. Staff, Admin and Corporate cash outflow was lower than the prior quarter by 11%.

Aggregate payments to related parties and their associates during the quarter was \$73,000 which includes directors' fees and superannuation.

Looking forward

Over the next 6 months, the Company is targeting to:

- Complete the BONIFF-SMEC piglet challenge study for enterotoxigenic Escherichia Coli
- Commence recruitment for the clinical study with GaRP in IBS patients;
- Commence recruitment of the clinical study with 3FDC in adult participants with moderate anxiety, stress or depression
- Announce a partnering deal for GaRP

"More than ever, the world is looking for safe and effective solutions to gut health. The early progress that Anatara has achieved in developing *evidence based* solutions for gastrointestinal diseases in both animals and humans is very encouraging. We have a very active program in place over the coming 6 to 12 months to progress the commercialisation of our health products, including pursuing a potential partnership agreement. We remain very encouraged about Anatara's future prospects.", concluded Mr Lydeamore.

This announcement has been authorised for release by the directors.

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For more information please contact:

General inquiries

Steven Lydeamore CEO, Anatara Lifesciences Ltd +61 (0) 438 027 172 slydeamore@anatara.com Sue MacLeman Chair, Anatara Lifesciences Ltd +61 (0) 437 211 200 smacleman@anatara.com

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 animal and human 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.

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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

31 March 2021

Con	solidated 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	(90)	(1,023)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	(10)	(47)
	(e) staff costs	(301)	(949)
	(f) administration and corporate costs	(216)	(617)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	3	9
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	888	979
1.8	Other (provide details if material)	45	89
1.9	Net cash from / (used in) operating activities	319	(1,559)

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)

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	-	-

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	(38)	3,032
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	1	(199)
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	(37)	2,833

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	3,675	2,682
4.2	Net cash from / (used in) operating activities (item 1.9 above)	319	(1,558)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	-

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)	(37)	2,833
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	Cash and cash equivalents at end of period	3,957	3,957

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	1,457	1,675
5.2	Call deposits	2,500	2,000
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)	3,957	3,675

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	73
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	uarter end	
7.6	Include in the box below a description of each rate, maturity date and whether it is secured facilities have been entered into or are proposinclude a note providing details of those facilities.	or unsecured. If any add osed to be entered into af	itional financing

8.	Estimated cash available for future operating activities	\$A'000
8.1	Net cash from / (used in) operating activities (item 1.9)	319
8.2	Cash and cash equivalents at quarter end (item 4.6)	3,957
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	3,957
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:

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

- 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 April 2021

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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.
- 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.