

29 April 2020

ASX Announcement

QUARTERLY CASH FLOW STATEMENT

Quarter highlights

- Phase I human clinical studies of AD-214 to commence in mid-2020; top-line safety results in healthy volunteers expected end 2020
- AdAlta funded to achieve forecast AD-214 milestones under a range of operating scenarios
- Efficacy of AD-214 demonstrated in gold standard animal model
- AD-214 pharmacokinetic and pharmacodynamic data in non-human primates (NHPs) supportive of target dosing regime in human clinical studies
- GE Healthcare (GEHC) collaboration to progress to Stage 3
- Manageable delays in development of PET imaging version of AD-214
- Strategy to fully leverage i-body platform released
- Board restructured; Non-Executive Director fees suspended
- \$4.14 million cash position as at 31 March 2020 (\$5.01 million at 31 December 2020)

Operations overview

During the March 2020 quarter AdAlta released positive pre-clinical data and made significant progress towards the key near term milestone of commencing a Phase I human clinical trial of lead product candidate AD-214. AD-214 is being developed to treat fibrotic diseases including Idiopathic Pulmonary Fibrosis (IPF). The Company notes recent reports that coronavirus infection (including COVID-19) is both particularly dangerous for patients already diagnosed with IPF and a risk factor for developing IPF in future. This is evidence of the value of improved therapies for this debilitating disease and encouragement for AdAlta to redouble efforts to introduce AD-214 to the clinic. The Company also notes that existing marketed IPF therapies are gaining regulatory approvals in other Interstitial Lung Diseases (ILDs), and patients suffering from ILDs will be included in the patient cohorts of the planned Phase I human clinical trials.

In response to the COVID-19 operating environment, AdAlta has developed flexible operating plans to support business continuity and adapt to further changes to ensure that the healthy volunteer part of the Phase I clinical trial and the development of the radio-labelled PET tracer can be achieved with existing cash resources. Preparation for the Phase I clinical trial of AD-214 remains on track to commence in mid-2020 and the collaboration with GE Healthcare is progressing to the next stage. However, the development of the PET tracer version of AD-214 has been delayed by closure of a key collaborator's laboratories.

AD-214 operating developments

AD-214 effective in gold standard bleomycin mouse model of IPF

The Company announced the positive outcome of a pre-clinical efficacy study demonstrating that AD-214 is effective in slowing progression of fibrosis in a bleomycin mouse model of IPF, the gold standard animal model for the disease.

In this model, bleomycin is administered to the lungs of mice, leading to the development of fibrosis. Drug candidates are evaluated for their ability to reduce fibrosis using a range of parameters including a key measure called the Ashcroft Score. Treatment with AD-214 at 1-30 mg/kg every second day and 10-30 mg/kg every fourth day resulted in a statistically significant reduction (improvement) in the Ashcroft Score of bleomycin-treated mice compared with mice receiving bleomycin alone.

This data is an important enabler to progress AD-214 into Phase I human clinical trials.

AD-214 pharmacokinetics/pharmacodynamics in NHPs support Phase I dose regime

Additional data from a Good Laboratory Practice (GLP) toxicology study of AD-214 in non-human primates (NHPs) conducted in the second half of 2019 were reported during the quarter.

The elimination half-life of AD-214 in NHPs (the time taken for blood plasma concentrations of AD-214 to halve) was 22-29 hours. Modelling suggests this could translate into a half-life in humans of up to 71 hours.

This study also showed that at AD-214 doses of 30 mg/kg and above, a high proportion of target receptors on circulating white blood cells were bound by AD-214 for at least three days. The longer that AD-214 occupies a large proportion of target receptors, the greater the likelihood and duration of therapeutic effects such as preventing fibroblast migration and other fibrotic mechanisms.

These results are supportive of potential therapeutic efficacy in humans of AD-214 doses of 10mg/kg administered at least weekly and possibly once every two weeks. Taken together with the bleomycin mouse efficacy data, they provide confidence that the Phase I human clinical trial (testing AD-214 doses from 0.1-20 mg/kg) includes clinically acceptable dose ranges that span the likely minimum therapeutic window and with a good safety margin.

AD-214 Phase I human clinical trial preparations on track for mid-2020 commencement

AdAlta's clinical trial partners continue to report that operating impacts from COVID-19 may be less severe in Phase I units and for healthy volunteer studies than for later stage trials, and that commencement of the Company's Phase I program in mid-2020 remains feasible, with top line healthy volunteer safety results anticipated by the end of 2020.

AdAlta's initial human clinical study of AD-214 is planned to include a single ascending dose part in healthy volunteers to evaluate safety and pharmacokinetics; followed by rapid movement to a single and multiple ascending dose part in ILD (including IPF) patients. Final preparations for ethics submission are underway, with first patient dosing planned for mid-2020. The bulk AD-214 drug substance has now been filled into vials for the Phase I clinical trial at PCI Pharma Services in Melbourne.

Development of radio-labelled AD-214 for PET imaging delayed

In December 2019, AdAlta announced the award of a A\$1 million Medical Research Future Fund (MRFF) Biomedical Translation Bridge (BTB) Grant to develop a radio-labelled version of AD-214 for PET imaging in clinical trials. This will enable receptor occupancy to be measured in the lungs of patients, a promising early indicator of potential for efficacy, during Phase I clinical trials.

Development of the imaging agent has commenced with positive early results. The laboratory of AdAlta's chelation chemistry collaborator has now been closed in response to COVID-19. While these closures will delay the development of the PET tracer, and potentially its introduction to the patient part of the Phase I program, the delay is manageable, and the initial healthy volunteer part of the trial does not require the PET tracer. The Company has been advised that the BTB Grant Funding Agreement is able to accommodate at least six months of delays and the total value of grant funds will not be affected. Pre-clinical development results (animal studies) are expected by end of 2020.

GE Healthcare (GEHC) partnership operating developments

AdAlta and GEHC have confirmed that their collaboration to discover i-body candidates as diagnostic imaging agents will proceed to Stage 3. AdAlta has to date received an initial milestone payment and research fees for Stage 1 and Stage 2 of the collaboration which are now complete. The research fee for Stage 3 will be paid in instalments. The phasing of these instalments will be adjusted in the event that reduced laboratory operations or laboratory closure in response to COVID-19 impact the duration of Stage 3.

Corporate developments

On 3 March 2020, AdAlta held an Investor Briefing to discuss its plans to grow the Company from the size and shape that it is today to being a much larger, highly revenue generative and valuable company. The strategy set out investments to be made:

- Progressing clinical development of AD-214 in IPF/ILD towards anticipated partnering windows at the end of Phase I or end of Phase II, and conducting pre-clinical development in additional indications
- Adding new pipeline products utilising i-bodies against G-protein coupled receptors (GPCRs) implicated in fibrosis, inflammation and cancer
- Entering new co-development partnerships to further expand the reach of the i-body platform
- In continuous improvement initiatives to extend i-body intellectual property protection and maximise AD-214 opportunities

A copy of the plan and videos from the briefing can be found on the Company's website (<http://adalta.com.au/ceo-update-investor-briefing-march-2020/>).

During the quarter, AdAlta announced the retirement of James Williams and Rosalind Wilson as Non-Executive Directors of the Company. James Williams was appointed an alternate director to Liddy McCall. The Company also announced the suspension of Non-Executive Director cash fees.

Financial update

AdAlta received A\$229,000 under the GEHC collaboration agreement during the quarter comprising Stage 2 research fees.

The Company also received A\$805,000 as the second advance against its accrued R&D Tax Incentive (RDTI) rebate under the facility with Radium Capital.

Operating cash outflows for the period were substantially reduced at A\$1.9 million (A\$3.9 million in the prior quarter) and were primarily for payments related to manufacturing, vialling and stability studies of AD-214, the bleomycin mouse study and other pre-clinical studies, clinical trial start-up costs and research costs, including those associated with the GE Healthcare collaboration. Outflows were A\$0.7 million lower than forecast for the period due primarily to delays in the receipt of invoices for existing pre-clinical studies and avoided requirement for additional pre-clinical studies. The prior quarter outflows were particularly high because they included the bulk of AD-214 manufacturing and GLP toxicology study costs.

The cash balance at the end of the quarter was \$4.14 million, down from \$5.02 million at the end of the previous quarter.

With prudent cash management actions in place and the deferral of the initiation of the strategic growth initiatives which were announced on 3 March, AdAlta is confident that existing cash resources are sufficient to achieve its forecast AD-214 milestones (top line safety results from the healthy volunteer part of the Phase I program and development of the radio-labelled PET imaging agent version of AD-214, currently anticipated by the end of 2020), including under scenarios where these key programs are delayed by the external operating environment by three months or more.

With near-term priorities funded and on track, the Company continues to actively evaluate options and opportunities to enable early initiation of our strategic growth initiatives.

Authorised for lodgement by:

Tim Oldham
CEO and Managing Director
April 2020

Notes to Editors

About AdAlta

AdAlta Limited is an Australian-based drug development company headquartered in Melbourne. The Company is using its proprietary technology platform to generate a promising new class of single domain antibody protein therapeutics, known as i-bodies, that have the potential to treat some of today's most challenging medical conditions. The technology mimics the shape and stability of a crucial antigen-binding domain that was discovered initially in sharks and then developed as a human protein. The result is a range of unique compounds, capable of uniquely interacting with previously difficult to access targets such as G-protein coupled receptors (GPCRs) that are implicated in many serious diseases.

AdAlta is currently preparing for its Phase 1 clinical studies for its lead i-body candidate, AD-214. The clinical program is targeted to commence in mid-2020 following finalisation of clinical trial design. AD-214 is being developed for the treatment of Idiopathic Pulmonary Fibrosis (IPF) and other human fibrotic diseases, for which current therapies are sub-optimal and there is a high-unmet medical need. The Company is also in collaborative partnerships to advance the development of its i-body platform. It has an agreement with GE Healthcare for diagnostic imaging agents against several drug targets, including Granzyme B.

AdAlta's strategy is to maximise the products developed using its next generation i-body platform by internally discovering and developing selected i-body enabled product candidates against GPCRs implicated in fibrosis, inflammation and cancer and partnering with other biopharmaceutical companies to develop product candidates against other classes of receptor, in other indications, and in other product formats.

Further information can be found at: <http://adalta.com.au>

For more information, please contact:

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Appendix 4C

Quarterly cash flow report for entities subject to Listing Rule 4.7B

Name of entity

ADALTA LIMITED

ABN

92 120 332 925

Quarter ended ("current quarter")

31 March 2020

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	229	616
1.2 Payments for		
(a) research and development	(1,485)	(7,341)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	-	-
(d) leased assets	-	-
(e) staff costs	(183)	(651)
(f) administration and corporate costs	(247)	(941)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	1	19
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	3,499
1.8 Other (provide details if material)	-	-
1.9 Net cash from / (used in) operating activities	(1,685)	(4,800)
2. Cash flows from investing activities		
2.1 Payments to acquire:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	-	(2)
(d) investments	-	-
(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	-	(2)

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	1,780
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	-	(154)
3.5	Proceeds from borrowings	805	1,765
3.6	Repayment of borrowings	-	-
3.7	Transaction costs related to loans and borrowings	(1)	(1)
3.8	Dividends paid	-	-
3.9	Other – (provide details if material)	-	-
3.10	Net cash from / (used in) financing activities	804	3,390

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	5,025	5,556
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,685)	(4,800)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	(2)

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)	804	3,390
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	Cash and cash equivalents at end of period	4,144	4,144

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	10	21
5.2	Call deposits	4,134	5,004
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)	4,144	5,025

6. Payments to related parties of the entity and their associates

- 6.1 Aggregate amount of payments to related parties and their associates included in item 1
- 6.2 Aggregate amount of payments to related parties and their associates included in item 2

**Current quarter
\$A'000**

180

-

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

The amount at 6.1 includes Director fees and salary (including superannuation) for executive director and related parties.

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	1,765	1,765
7.2 Credit standby arrangements	-	-
7.3 Other (please specify)	-	-
7.4 Total financing facilities	1,765	1,765

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.

The loan facility is with Innovation Structured Finance Co., LLC serviced via Radium Capital and is an advance on 80% of the Company's R&D Tax Incentive (RDTI) for the financial year ending 30 June 2020. The interest rate for the loan facility is 15% per annum. Repayment is timed to coincide with receipt of AdAlta's 2020FY RDTI refund. The facility has been in place since 20 December 2019. An initial advance under the facility of \$960,231 was received on 20 December 2019, with a further \$805,118 received on 23 March 2020 (total amount borrowed: \$1,765,349).

8. Estimated cash available for future operating activities	\$A'000
8.1 Net cash from / (used in) operating activities (Item 1.9)	(1,686)
8.2 Cash and cash equivalents at quarter end (Item 4.6)	4,144
8.3 Unused finance facilities available at quarter end (Item 7.5)	-
8.4 Total available funding (Item 8.2 + Item 8.3)	4,144
8.5 Estimated quarters of funding available (Item 8.4 divided by Item 8.1)	2.5

8.6 If Item 8.5 is less than 2 quarters, please provide answers to the following questions:

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:

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:

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:

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.

29 April 2020

Date:

By the Board.

Authorised by:
(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.