



ASX Announcement

27 January 2021

Quarterly Activity Report Q2 FY21

Highlights

- COVID-19¹ point-of-care testing continues to drive revenue and present significant opportunities for Atomo moving into the second half of FY21:
 - **North America:** First shipments of 259,200 devices sent to Access Bio; with first revenue from Access Bio expected in Q3 FY21
 - Access Bio completed FDA submission for an EUA for its rapid antibody test on the Atomo platform
 - **Australia:** Strong first sales of the TGA-approved AtomoRapid™ COVID-19 rapid antibody test; first shipment of TGA-approved COVID-19 rapid antigen test received to commence sales in the Australian market
 - **Europe:** NG Biotech ordered a further two containers; progress made with its submission for securing CE Mark self-test approval in Europe
- **HIV business:** validation of Atomo facility in South Africa and a new Australian agreement
- **OEM business:** production capacity and sales of the Pascal platform increase to meet demand
- **Cash receipts** from customers as at 31 December 2020 of \$2.8m, up strongly on the previous corresponding period (\$346k), bringing total receipts for H1 FY21 to \$5.8m. Cash injection of \$1.0m received under the R&D tax rebate
- Atomo finished the quarter debt-free and with **cash on hand** of \$24.7m
- **Revenues** for Q2 FY21 (unaudited) approximately \$2m, bringing total revenue for H1 FY21 (unaudited) to \$4.5m

SYDNEY Australia Wednesday, 27 January 2021 – Australian rapid blood test company Atomo Diagnostics Limited (ASX: AT1) (**Atomo**) is pleased to release its Appendix 4C and quarterly activities report for the three-month period ended 31 December 2020 (Q2 FY21). Atomo's cash position continues to be strong as customer receipts, and receipt of the Company's R&D tax rebate supported ongoing investment in inventory, manufacturing capacity and R&D.

¹ COVID-19 rapid testing detects SARS-COV-2, the virus that causes COVID-19



Atomo's co-founder and Managing Director John Kelly said, *"During the quarter, Atomo continued to position itself for growth. Regulatory activity included supporting Access Bio with completion of its FDA submission for EUA for its antibody test on the Atomo platform and obtaining approval for Atomo's rapid antigen test from the TGA. Manufacturing capacity scale-up continued investment in R&D and the assessment of potential new products and market opportunities."*

"With significant sales secured in Australia of our AtomoRapid™ COVID-19 rapid antibody tests and stock now in-country of our COVID-19 rapid antigen test, we are in a strong position to continue to scale up our Australian business, as well as supporting Australia's management of the pandemic as it enters the next phase and the vaccination programme gets underway. We continue to actively engage with Australian health authorities to encourage the continued expansion of rapid testing as a critical element in responding to the pandemic."

"More broadly, it is expected that COVID-19 testing will continue to be an important part of the global response to the pandemic, and that this is likely to continue during the period where the vaccine is rolled out around the world. We have seen a commitment from the Biden Administration to \$50bn of funding for testing across the US and indications are that testing will have a role to play alongside vaccinations to confirm their effectiveness and provide documentation to support travel and return to work. As a result we expect COVID-19 testing to be an important part of Atomo's business for a number of years."

COVID-19

During the quarter Atomo's COVID-19-related activities were extensive across North America, Europe, and Australia.

North America:

In the US, Atomo provided support to Access Bio in finalising its submission for Emergency Use Authorisation (**EUA**) for its antibody test on the Atomo platform from the US Food & Drug Administration (**US FDA**). Access Bio is seeking a Point of Care Clinical Laboratory Improvement Amendments (**CLIA**) waiver that would allow it to sell the product into a broader range of settings than the typical EUA granted to other antibody test providers. As a result, the FDA required Access Bio to conduct additional usability studies in these settings which required additional time, delaying the submission. Access Bio has confirmed that the submission has been lodged and the application is now under consideration by the FDA with a response expected in the current quarter (Q3 FY21).



The initial order for 259,200 Atomo devices placed by Access Bio in Q2 FY20 in anticipation of US FDA approval being obtained was dispatched during the quarter and the revenue contribution will be recognised in the current quarter. The Access Bio agreement provides for a revenue share with Atomo that will see Atomo receive a guaranteed minimum share of revenue, whilst also providing Atomo with exposure to upside where Access Bio achieves prices above that minimum guarantee. The agreement between Atomo and Access Bio further provides that Access Bio must order 2 million Atomo devices by 30 September 2021 or pay a material shortfall fee, which is in excess of the minimum per unit price. The take-or-pay commitment is not subject to Access Bio obtaining FDA approval.

Australia:

During the quarter, Atomo launched its TGA approved AtomoRapid™ COVID-19 (IgG/IgM) antibody test for sale in the Australian market and achieved sales of \$394k across a range of professional testing and corporate channels. Following receipt of TGA approval for the Atomo rapid COVID-19 antigen test, produced for Atomo by Access Bio in the US, Atomo has commenced supply into the Australian market. Sales efforts ramped up over the December quarter, with an additional dedicated senior sales resource recruited locally to support promotion of Atomo products in the region.

Europe:

NG Biotech (NG) remains focused on sales of its COVID-19 antibody test on the Atomo platform. The agreement between Atomo and NG required NG to purchase a minimum of 2.5m Atomo devices between March 2020 and 31 December 2020, in order to extend its exclusivity arrangement in France and the UK beyond 31 December 2020. During that period, NG ordered approximately 1.9m Atomo devices, including 259,200 units during Q2 FY21. NG continues to pursue various sales channels, including being well-progressed towards securing European CE Mark self-test approval which will allow access to a premium market with significantly less competition. Atomo will continue to supply to NG on a non-exclusive basis moving into CY21. Atomo has had a number of approaches from parties interested in commercialising their COVID-19 antibody tests on the Atomo platform in the European market and is re-engaging with these parties during the quarter.

HIV

The HIV business continues to progress, with the validation of the Atomo facility in South Africa and a new Australian supply agreement entered into with PrEP Health. Atomo has



expectations of continued traction in the emerging global health market via its strategic partnership with Mylan Pharmaceutical.

Original Equipment Manufacturing (OEM)

Production of Atomo's Pascal platform increased during the quarter in response to growing demand, particularly from diagnostic company Lumos Diagnostics, which is commercialising its FebriDx rapid blood test. The test, which is commercialised on the Atomo Pascal platform, detects viral vs bacterial infections.

Atomo continues to seek new OEM opportunities as production capacity becomes available across Pascal and Galileo, and with the anticipated launch of the Elion platform. See Appendix B for further information.

During the quarter, Atomo welcomed the appointment of an additional senior position in the US, with extensive experience in the rapid diagnostics market, to assist in driving our existing OEM and finished product sales efforts in the region.

Manufacturing Capacity

Atomo's manufacturing expansion continued during the quarter, with total unit production capacity further increasing across both the Galileo and Pascal platforms. By the end of Q2 FY21, available capacity for production of Galileo devices had increased to 1.3m units per month and 300k per month for Pascal devices.

Atomo progressed the evolution of its proprietary blister machine with continued investment throughout the quarter. Construction of the second machine is well progressed and anticipated to be commissioned in early FY22. When completed, the new blister machine will increase total Pascal production capacity to 800k per month.

Financials

Cash receipts from customers in Q2 FY21 totalled \$2.8m, bringing cash receipts for H1 FY20 to \$5.8m.

Q2 FY21 (unaudited) sales were approximately \$2.0 million across the business. Australian sales of the COVID-19 antibody test were strong, totalling approximately \$400k. Robust sales to Lumos supported additional growth in the OEM segment. Shipments to Access Bio of



259,200 units are not reflected in revenue to-date. These shipments will be booked as revenue in Q3 FY21.

Product manufacturing and operating cash outflows increased during the quarter as the company continued to restock and build inventory throughout the quarter in anticipation of continued strong growth in H2 FY21. This includes the purchase of stock of the TGA-approved AtomoRapid™ COVID-19 rapid antibody test for sale into Australia.

Capitalised expenditure related to R&D of \$877k, reflected continued investment in the next-generation blister machine development. Further, as manufacturing capacity ramped up, property, plant and equipment expenditure increased to \$695k for the quarter.

In accordance with ASX Listing Rule 4.7B, Atomo advises that an amount of \$183k was paid during the quarter to Atomo Directors in salary and director's fees.

Atomo's cash balance at the end of the quarter was \$24.7m.

Key Priorities

Atomo continues to focus on core growth drivers, including:

- Assisting Access Bio in securing an EUA from the FDA for its COVID-19 rapid antibody test on the Atomo platform
- Ramping up supply of COVID-19 rapid antibody tests to Access Bio under the take-or-pay agreement
- Driving continued growth of COVID-19 antibody and antigen rapid test sales in the Australian market
- Driving sales in the growing global health HIV market
- Continue to support the OEM market, including meeting demand from Lumos for its FebriDx product as well as pursuing new OEM contractual opportunities

Comparison of actual expenditure against use of funds statement

Appendix A provides a summary of actual expenditure, compared to the estimated use of funds set out in Atomo's IPO prospectus dated 4 March 2020 (**Prospectus**), in accordance with ASX Listing Rule 4.7C. Cash expenditure during the quarter was consistent with the use of funds set out in the Prospectus. Refer to the notes to the summary table in Appendix A for further information in relation to each of the categories of expenditure.



For more information, please contact:

Jane Lowe

IR Department

jane.lowe@irdepartment.com.au

Phone: +61 411 117 774

John Kelly

Atomo Diagnostics

john.kelly@atomodiagnostics.com

Phone: +61 401 922 279

This announcement was authorised by the Board of Directors.

About Atomo

Atomo is an Australian medical device company supplying unique, integrated rapid diagnostic test (RDT) devices to the global diagnostic market. Atomo's patented devices simplify testing procedures and enhance usability for professional users and untrained self-testers. The Company has supply agreements in place for tests targeting infectious diseases including COVID-19, viral vs bacterial differentiation and female health.

See more at www.atomodiagnostics.com.

Forward looking statements

This announcement may contain forward looking statements which may be identified by words such as "believes", "considers", "could", "estimates", "expects", "intends", "may", and other similar words that involve risks and uncertainties. Such statements are not guarantees of future performance and involve known and unknown risks, uncertainties, assumptions and other important factors, many of which are beyond the control of Atomo or its Directors and management, and could cause Atomo's actual results and circumstances to differ materially from the results and circumstances expressed or anticipated in these statements. The Directors cannot and do not give any assurance that the results, performance or achievements expressed or implied by the forward-looking statements contained in this announcement will actually occur and investors are cautioned not to place undue reliance on these forward-looking statements



Appendix A

In accordance with ASX Listing Rule 4.7C Atomo provides the following use of funds information:

Use of funds	Prospectus	Actual Funds Deployed		Ref
		Actual Accumulated	As a % of Prospectus	
	(A\$'000)	(A\$'000)	%	
Expansion of Manufacturing & Distribution	11,700	1,406	12.0%	1
Research & Development and Product Commercialisation	11,025	2,803	25.4%	2
GHIF Loan Repayment (Including Outstanding Interest)	7,010	7,746	110.5%	3
Administrative Costs	2,446	589	24.1%	4
Market Expansion	1,600	197	12.3%	5
Interest on Convertible Notes	900	756	84.0%	6
Working Capital & Operating Costs	5,055	(278)	-5.5%	7
Costs of the Offer	2,704	1,897	70.2%	8
TOTAL (INCLUDING EXISTING CASH)	42,440	15,116	35.6%	9

Ref	Comment
1	Capacity ramp up to support accelerated growth
2	Includes capitalised R&D related to blister machine design and engineering
3	Forex movements. No further outflows beyond Q4 FY20
4	Includes incremental public company costs
5	Excludes expenses related to new market entry
6	Actual less than estimate due to IPO timing. No further outflows beyond Q4 FY20
7	Net working capital balance after accounting for outflows for operating costs and overheads during the period and receipts of \$7.7m from customers since IPO
8	Excludes cash outflows pre-IPO relating to costs of the offer amounting to \$1.2 million. No further outflows beyond Q4 FY20
9	Total of \$42.44m includes existing cash of \$12.44m on hand as at 31 December 2019 as per Prospectus. Total expenditure includes net working capital movements from 31 December 2019 to IPO of \$1.3m

atomo

Appendix B

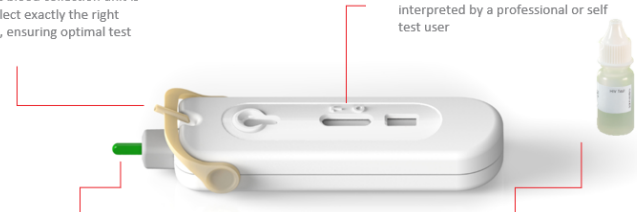
GALILEO

Accurate Blood Collection

The easy-to-use blood collection unit is designed to collect exactly the right sample volume, ensuring optimal test performance.

Easy-to-Read Results

The results can be easily read and interpreted by a professional or self test user



Built-in Safety Lancet

The auto-retracting safety lancet eliminates the risk of hazardous sharps injuries by locking the needle inside the device after use for safe disposal.

Buffer Delivery

The buffer solution to run the test is manually delivered using a standard buffer bottle

PASCAL

Accurate Blood Collection

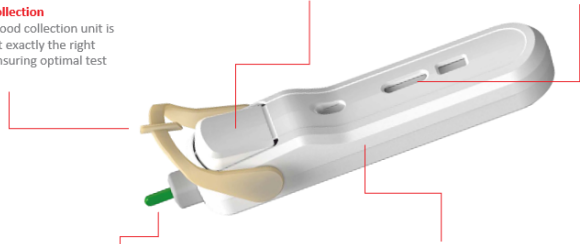
The easy-to-use blood collection unit is designed to collect exactly the right sample volume, ensuring optimal test performance.

Integrated Buffer Delivery

The unique, patented mechanism delivers the required quantity of chase buffer at the touch of a button.

Easy-to-Read Results

The results can be easily read and interpreted by a professional or self test user



Built-in Safety Lancet

The auto-retracting safety lancet eliminates the risk of hazardous sharps injuries by locking the needle inside the device after use for safe disposal.

Test Strip

The device can be adapted to accommodate most blood-based lateral flow test strips.

ELION

Built-in safety lancet
Ergonomic lancet cover supports ease-of-use and further enhances device safety.

Easy-to-Read Results
The results can be easily read and interpreted by a professional or self test user



Integrated buffer delivery
Activation button delivers blood sample and buffer to the test strip, removing a user step.

Blood collection and delivery unit
Unique, intuitive design simplifies blood collection procedure for the lay user by providing clear 'target' for the blood droplet.

Appendix 4C

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

Name of Entity

Atomo Diagnostics Limited

ABN

37 142 925 684

Quarter Ended ("current quarter")

31 December 2020

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	2,769	5,805
1.2 Payments for		
(a) research and development	(303)	(477)
(b) product manufacturing and operating costs	(2,435)	(3,625)
(c) advertising and marketing	(4)	(4)
(d) leased assets	(1)	(3)
(e) staff costs	(819)	(1,701)
(f) administration and corporate costs	(873)	(1,459)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	29	68
1.5 Interest and other costs of finance paid	(1)	(3)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	1,107	1,203
1.8 Other (provide details if material)	-	-
1.9 Net cash from / (used in) operating activities	(532)	(193)
2. Cash flows from investing activities		
2.1 Payments to acquire or for:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	(695)	(778)
(d) investments	-	-
(e) intellectual property	(877)	(1,874)
(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) operating activities	(1,572)	(2,652)
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	479	625
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(10)	(10)
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	(27)	(52)
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	441	562
4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	26,345	27,104
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(532)	(193)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(1,572)	(2,652)

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)	441	562
4.5	Effect of movement in exchange rates on cash held	9	(131)
4.6	Cash and cash equivalents at end of period	24,691	24,691

5. Reconciliation of cash and cash equivalents		Current Quarter A\$'000	Previous Quarter A\$'000
at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts			
5.1	Bank balances	24,691	26,345
5.2	Term 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)	24,691	26,345

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	183
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-
<p><i>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.</i></p>		

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

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 arrangement	-	-
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)	(532)
8.2 Cash and cash equivalents at quarter end (Item 4.6)	24,691
8.3 Unused finance facilities available at quarter end (Item 7.5)	-
8.4 Total available funding (Item 8.2 + Item 8.3)	24,691
8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)	46

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: Not applicable.

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: Not applicable.

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: Not applicable.

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: 27/01/2021

Authorised by:The Board
(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.