

Quarterly Activity Report Q3 FY21

Highlights

- **HIV business:** agreement executed between Unitaid and Viatris (formerly Mylan) with support from Atomo. Unitaid has advised that it intends to support the supply of up to one million HIV self-tests to LMICs to further stimulate in-country demand for self-testing, with Viatris/Atomo having been selected as one of the providers for this programme
- **COVID-19¹** point-of-care testing activities continued throughout the quarter:
 - **North America:** First revenue booked from Access Bio during Q3 FY21 with FDA EUA pending for its rapid antibody test on the Atomo Galileo platform
 - **Australia:** Continued business in Australia in COVID-19 rapid antibody test sales and launch/ initial sales of COVID-19 rapid antigen tests. Pilot programmes with aged care providers and national sports organisations under way
- **OEM business:** approaches received from two large US listed diagnostic companies interested in accessing Atomo's integrated platform technology, and continued progress with manufacture of next generation blister machine to support Pascal capacity scale-up
- **US market entry:** specialist consulting firm Bondi Partners engaged to provide strategic advisory and commercial engagement activities in support of Atomo's US go-to-market strategy
- **Cash receipts** from customers for Q3 FY21 of \$1.5m, bringing total cash receipts for YTD FY21 to \$7.3m
- **Revenues** for Q2 FY21 (unaudited) approximately \$1.5m, bringing total revenue for YTD FY21 (unaudited) to \$6.1m
- Atomo finished the quarter debt-free and with **cash on hand** of \$21.4m

SYDNEY Australia Friday, 30 April 2021 – Australian rapid 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 March 2021 (Q3 FY21).

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

HIV – Multi-year supply agreement executed between Viatris and Unitaid

During the quarter, Atomo was pleased to announce the execution of a multi-year agreement between Unitaid and Viatris (through its subsidiary Mylan), with support from Atomo as exclusive product manufacturer and supplier of its WHO pre-qualified HIV self-tests to Viatris.

Atomo's co-founder and Managing Director, John Kelly, said, "The Viatris and Atomo teams have worked tirelessly over a long period of time to achieve this major milestone. With the COVID-19 pandemic continuing to cause significant disruption to healthcare facilities globally, self-testing is being increasingly recognised as a reliable and scalable channel to improve HIV testing rates, and this agreement is recognition of Unitaid's commitment to that goal. We are delighted to be recognised as a key participant in what will be a significantly expanded rollout of HIV self-testing in the coming years."

The World Health Organisation (WHO) has estimated the global health HIV self-testing market to be 11 million tests in 2021, rising to 29 million tests by 2025¹.

The agreement is a major market expansion of HIV self-testing, with commitments to make testing available in 135 eligible countries. Unitaid has notified the market that it intends to support the initial supply of up to one million HIV self-tests to further stimulate in-country demand for self-testing, with Viatris/Atomo having been selected as one of only two providers for this program. Atomo's wholly owned and fully qualified HIV facility in South Africa, has now commenced volume manufacturing to support this programme.

COVID-19 – Continued sales

During the quarter Atomo continued to be active in COVID-19 markets globally. In the US, Access Bio has confirmed that its submission for Emergency Use Authorisation (**EUA**) for its antibody test on the Atomo platform to the US Food & Drug Administration (**US FDA**) remains under review, with no further information being requested by the US FDA. An initial order for 259,200 Atomo devices was placed by Access Bio in Q2 FY21 and accordingly, first revenue under this contract was booked during Q3 FY21.

¹ Johnson C et al (2020). HIV self-testing market forecasting. World Health Organization - Diagnostic Manufacturer Meeting. Power Point presentation (virtual meeting). 20th October 2020.



Atomo continued to expand its marketing activities in Australia during the quarter for both the AtomoRapid™ COVID-19 (IgG/IgM) antibody and the Atomo rapid COVID-19 antigen test both of which have been added to the Australian Register of Therapeutic Goods for local supply.

Demand for Atomo's rapid antibody test remains steady and the launch of the rapid antigen test has commenced with Atomo supporting Australian sporting teams implement rapid antigen test screening programmes in training camps and at pre-selection events ahead of the Olympic Games to be held in Tokyo in July 2021. Atomo has been actively engaged with pilot screening programmes at two aged care facilities, one in Victoria and one in Queensland, with a view to rolling out the programme more broadly following the pilot.

Atomo has continued to engage with potential partners in other markets. Discussions with a large listed Chinese company have progressed, with a view to targeting a broader collaboration beyond COVID-19. This potential partner is keen to leverage the usability of the Atomo devices in the growing China self-test and at-home testing markets, as well as collaborating across key LMICs where they have significant business. Atomo is also in discussions in relation to providing testing support to the Indian market given the current scale of the impact of the pandemic in India.

Original Equipment Manufacturing (OEM)

The primary OEM activity during the quarter was to continue to supply Pascal devices to long term customer Lumos Diagnostics. In addition, and in response to ongoing outbound activity to promote the Atomo platform, Atomo has received a number of approaches during the quarter from major diagnostics companies interested in better understanding Atomo's unique technology and its potential applicability to their rapid test businesses. As the COVID-19 pandemic enters the next phase, with the vaccine roll-out accelerating particularly in the US and Europe, market participants have begun to look beyond the pandemic to better understand and anticipate the future landscape for point of care testing.

US Market entry

As recently announced, Atomo is actively prioritising the scale up of its US business and has engaged Bondi Partners to assist with the development and execution of its US market entry strategy. This is consistent with Atomo's broader market expansion plans to leverage its unique proprietary technology in the US market, which accounts for around half of the global point of care diagnostics market. Atomo has also been working with technical/diagnostic



industry experts, Halteres Consulting, for the last several months, who have assisted with establishing a clear picture of the US diagnostics landscape and emerging opportunities. With the assistance of the complementary skill sets of Bondi Partners and Halteres Group, together with the in-house team, Atomo is well placed to establish its US business operations in the coming year.

Financials

Cash receipts from customers in Q3 FY21 totalled \$1.5m, bringing cash receipts for the year-to-date (YTD) to \$7.3m.

Q3 FY21 (unaudited) sales were approximately \$1.5 million across the business. Strong sales to Lumos were repeated within the quarter in conjunction with sales generated by the shipment of 259,200 units to Access Bio.

Product manufacturing and operating cash outflows continue to remain a focus as Atomo restocks and builds inventory for future growth.

Capitalised expenditure related to R&D of \$466k, reflected continued investment in the next-generation blister machine development. Further, as manufacturing capacity ramped up, property, plant and equipment expenditure increased to \$1.57m 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 \$21.3m.

Key Priorities

As Atomo approaches FY22, the clear priority areas include:

- Scale up of the HIV business and expansion of the Viatris business under the Unitaid program covering more than 130 countries
- Continue to maximise COVID-19 global opportunities
- Expand Atomo's US business



- Secure new OEM contracts including strategic partnerships with larger diagnostics companies wishing to improve the usability and marketability of their POCT products

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 statement 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

For personal use only

Appendix A

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

Use of funds	Prospectus (A\$'000)	Actual Funds Deployed		Ref
		Actual Accumulated (A\$'000)	As a % of Prospectus %	
Expansion of Manufacturing & Distribution	11,700	2,974	25.4%	1
Research & Development and Product Commercialisation	11,025	3,306	30.0%	2
GHIF Loan Repayment (Including Outstanding Interest)	7,010	7,746	110.5%	3
Administrative Costs	2,446	765	31.3%	4
Market Expansion	1,600	270	16.9%	5
Interest on Convertible Notes	900	756	84.0%	6
Working Capital & Operating Costs	5,055	572	11.3%	7
Costs of the Offer	2,704	1,897	70.2%	8
TOTAL (INCLUDING EXISTING CASH)	42,440	18,287	43.1%	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 cash receipts 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

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 March 2021

Consolidated statement of cash flows	Current Quarter A\$'000	Year to date (9months) A\$'000
1. Cash flows from operating activities		
1.1 Receipts from customers	1,489	7,294
1.2 Payments for		
(a) research and development	(37)	(514)
(b) product manufacturing and operating costs	(1,207)	(4,831)
(c) advertising and marketing	(13)	(17)
(d) leased assets	(1)	(4)
(e) staff costs	(829)	(2,530)
(f) administration and corporate costs	(552)	(2,011)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	14	82
1.5 Interest and other costs of finance paid	-	(3)
1.6 Income taxes paid	-	
1.7 Government grants and tax incentives	31	1,234
1.8 Other (provide details if material)		
1.9 Net cash from / (used in) operating activities	(1,106)	(1,299)
2. Cash flows from investing activities		
2.1 Payments to acquire or for:		
(a) entities	-	
(b) businesses	-	
(c) property, plant and equipment	(1,568)	(2,346)
(d) investments	-	-
(e) intellectual property	(466)	(2,340)
(f) other non-current assets	-	

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

Consolidated statement of cash flows		Current Quarter A\$'000	Year to date (9months) 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	(2,034)	(4,686)
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	-	625
3.4	Transaction costs related to issues of equity securities or convertible debt securities	-	(10)
3.5	Proceeds from borrowings	-	
3.6	Repayment of borrowings	(30)	(83)
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	(30)	532
4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	24,691	27,104
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,106)	(1,299)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(2,034)	(4,686)

Consolidated statement of cash flows		Current Quarter A\$'000	Year to date (9months) A\$'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(30)	532
4.5	Effect of movement in exchange rates on cash held	(132)	(263)
4.6	Cash and cash equivalents at end of period	21,388	21,388

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	21,388	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)	21,388	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	-
<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>		

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

7.1 Loan facilities

7.2 Credit standby arrangement

7.3 Other (please specify)

7.4 **Total financing facilities**

Total facility amount at quarter end A\$'000	Amount drawn at quarter end A\$'000
-	-
-	-
-	-
-	-

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)	(1,106)
8.2 Cash and cash equivalents at quarter end (Item 4.6)	21,388
8.3 Unused finance facilities available at quarter end (Item 7.5)	-
8.4 Total available funding (Item 8.2 + Item 8.3)	21,388
8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)	19

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: 30 April 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.