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ASX Announcement **29 July 2021**

Quarterly Activity Report Q4 FY21

Highlights

- **HIV:** Viatris and Atomo announce securing Unitaid agreement. First shipments delivered end of Q4 FY21
- **COVID-19**[1] point-of-care testing:
  - **North America:** Access Bio receives FDA EUA point of care (POC) approval for the Carestart COVID-19 Antibody test utilising the Atomo Galileo platform
  - **Australia:** Material increase in interest in Atomo's COVID-19 rapid test products locally driven by lockdowns and new testing requirements to support essential activities
- **OEM business:** Ongoing commercial and technical engagement now underway with several large multinational diagnostic companies seeking access to Atomo's rapid test technologies and usability expertise
- **US market entry:** Business development/commercial resourcing and local entity infrastructure currently being established
- **Cash receipts** from customers for Q4 FY21 of $717k, bringing total cash receipts for FY21 to ~$8m and **Q4 FY21 revenues** (unaudited) of approximately $670k, bringing total revenue for FY21 (unaudited) to $6.7m, 25% up compared with FY20 revenues ($5.4m)
- Atomo finished the quarter debt-free and with **cash on hand** of $17.95m

SYDNEY Australia Thursday, 29 July 2021 – Australian rapid test company Atomo Diagnostics Limited (ASX: AT1) (**Atomo**) is pleased to release its Appendix 4C and quarterly activity report for the three-month period ended 30 June 2021 (Q4 FY21).

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

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HIV – Production and Supply ramp up to support demand

As announced on 30 April 2021, Viatris (through its subsidiary Mylan) and Unitaid have entered into a multi-year agreement to expand access to HIV self-testing in low and middle-income countries (**LMIC)** under which Viatris will supply the *Mylan HIV Self-Test*, which is designed and manufactured by Atomo to 135 LMIC countries.

An initial order of 250,000 Atomo manufactured HIV Self-Tests was received late in Q4 FY21 from Viatris to fulfill initial demand under the Unitaid purchasing program, in which the Atomo manufactured *Mylan HIV Self-Test* was one of only two products selected. First shipment was delivered at the end of the quarter, with the majority of the order to be delivered in Q1 FY22.

In order to support this initial order, and in anticipation of ongoing growth in demand through FY22, Atomo has commenced ramp-up of production, added additional assembly and packaging lines, and hired and trained further staff at its South African facility.

Atomo's co-founder and Managing Director, John Kelly, said, "Viatris has commenced broad engagement with the global health market to begin a roll out of our HIV Self-Test in multiple countries to meet the growing demand for HIV self-testing. We are very excited to be ramping up our production facility to support this roll-out and to send out our first shipments to Viatris late in the quarter. We are now well placed to support anticipated growth as we commence the new financial year."

COVID-19 – US FDA EUA received for CareStart EZ COVID-19 IgM/IgG antibody test on Atomo platform

As disclosed in the Q3 FY21 Quarterly Activity Report, Atomo received an initial order from Access Bio for 260,000 Atomo devices in preparation for the US launch of the CareStart™ EZ COVID-19 IgM/IgG antibody test which is integrated with the Atomo Galileo device. Emergency Use Authorisation (**EUA**) was received by Access Bio from the US Food & Drug Administration (**US FDA**) during the quarter. The EUA provides Access Bio with approval for distribution in point-of-care settings such as doctor's offices, hospitals and emergency rooms in the United States. No further orders for Galileo devices were received from Access Bio during the period however it is noted that FDA product approval was granted at the very end of the quarter, on 26 June 2021. Discussions with Access Bio are ongoing in relation to the delivery schedule through to 30 September 2021. Atomo notes the take-or-pay commitment requires Access Bio to order and sell 2 million units by 30 September 2021, or pay a shortfall fee. Please refer to Atomo's announcement on 28 July 2020.

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Atomo's Managing Director John Kelly said, "We are delighted that our integrated test device has enabled Access Bio to secure EUA for point-of-care use from the US FDA. This now enables Access Bio to commence the rollout of the product in the US. It also establishes a clear precedent for future potential product approvals in the US to be sought either directly by Atomo for our own products or by our current and future OEM partners looking to take our user- friendly devices through FDA approval processes for their own suite of tests."

COVID-19 tests - Australia

In Australia, there has been increased interest in Atomo's COVID-19 rapid tests, in particular the Atomo COVID-19 rapid antigen test.

Atomo has directly engaged with the Australian Aged Care market to pioneer Australia's first aged care COVID-19 rapid antigen screening program. The Company also continued to work with various Australian Olympic Sporting teams in their pre-tournament training camps and qualifying events to keep them COVID-safe in preparation for Tokyo.

The slow vaccine roll-out and the recent national lockdowns, has significantly increased interest in rapid COVID-19 antigen testing. As such, Atomo has engaged with numerous industrial companies and national aged care providers seeking to implement screening programmes to keep essential workforces COVID-safe and open for business, rather than relying on high cost and slow response times from centralised lab facilities.

Interest in Atomo's rapid testing solutions has further materially increased since the end of the quarter as the situation has become more urgent and NSW in particular starts to adopt rapid antigen testing more broadly.

Original Equipment Manufacturing (OEM)

Engagement with potential new OEM partners continued during Q4 FY21. Diagnostic companies, particularly in the US, continue to seek to position themselves to access opportunities, sustain growth and enter markets beyond COVID-19. Point-of-care and at-home testing has been the fastest growing segment of the diagnostics market through the pandemic and this trend is expected to continue.

Atomo has noticed a significant increase in interest from larger diagnostics companies that are seeking rapid test solutions that are simple to use and reliable. These parties are attracted to Atomo's proven, simple to use diagnostic devices that do not compromise on quality and

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are ideally suited to use in point-of-care settings and at home. Atomo's core IP that enables accurate sample collection, accurate delivery of buffer and reduced user-error is of particular interest to these potential partners as they look to develop new tests and products for market. This includes applications for Atomo's technology in tests using samples beyond blood, such as saliva and nasal swabs.

We were pleased to see the successful listing of our strategic partner, Lumos Diagnostics in July, and remain hopeful that it will soon receive US FDA approval for its FebriDx diagnostic test, which utilises Atomo's Pascal rapid test device.

US Market entry

Given the US provides the greatest opportunity in the point-of-care and at home diagnostics markets, Atomo continues to push ahead with its US market entry strategy. The company is working with Bondi Partners and Halteres Associates to engage with key players in the US market and the recruitment of a US based senior business development resource to support this activity. Managing Director John Kelly said: "It is early days, but we are excited by the level of enquiries we are already experiencing in the US market."

Financials

Cash receipts from customers in Q4 FY21 totalled $717k, bringing cash receipts for the full year to $8.01m. A further ~$750k was received from customers shortly after the close of the period.

The exercise of options during the quarter resulted in a further $496k in cash receipts.

Sales in Q4 FY21 (unaudited) were approximately $670k across the business. Revenues (unaudited) for FY21 total $6.7m, up by 25% compared with FY20 ($5.4m). With the Access Bio FDA approval and the initial HIV orders from Viatris both being delivered late in the quarter, we would expect increased contributions in the coming periods.

The ramp up in production activity in South Africa led to increased expenditure on production and manufacturing. Continued investment was made during the period in the next generation blister machine which is an essential manufacturing unit to support growth in our OEM business.

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.

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Atomo's cash balance at the end of the quarter was $17.95m.

Key Priorities

As the Company enters FY22, our key priorities remain unchanged and include:

- Expansion of the Viatris business under the Unitaid program covering more than 135 countries
- Continue to maximise COVID-19 global opportunities, including meeting increased demand for rapid antigen testing in Australia
- Expand Atomo's US business and customer base
- Secure new OEM contracts including strategic partnerships with larger diagnostics companies wishing to improve the usability and marketability of their POCT products

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.

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This announcement was authorised by the Board of Directors.

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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

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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	3,739	32.0%	1
Research & Development and Product Commercialisation	11,025	4,051	36.7%	2
GHIF Loan Repayment (Including Outstanding Interest)	7,010	7,746	110.5%	3
Administrative Costs	2,446	961	39.3%	4
Market Expansion	1,600	619	38.7%	5
Interest on Convertible Notes	900	756	84.0%	6
Working Capital & Operating Costs	5,055	2,222	44.0%	7
Costs of the Offer	2,704	1,897	70.2%	8
TOTAL (INCLUDING EXISTING CASH)	**42,440**	**21,991**	**51.8%**	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