



ASX Announcement

25 October 2021

## Quarterly Activity Report Q1 FY22

### Highlights

- **Significant increase in COVID-19<sup>1</sup> rapid antigen test sales:** Fundamentally changed rapid test landscape in Australia due to the Delta variant outbreak and adoption of rapid testing as a pillar of public health policy
- **New agreement with Access Bio:** Right to secure up to 20m COVID-19 rapid antigen tests. One-off payment from Access Bio of US\$1.72m (A\$2.4m), received post-quarter end
- **HIV business:** Delivered initial Viatrix order of 250,000 HIV Self-Test products with subsequent orders received late in Q1 for India and two other countries
- **Cash receipts and revenues:** Cash receipts of \$2.2m from customers during the quarter, and unaudited revenue of \$2.4m
- Atomo finished the quarter debt-free and with **cash on hand** of \$15.2m

**SYDNEY Australia Monday, 25 October 2021** – Atomo Diagnostics Limited (ASX: AT1) (**Atomo**) is pleased to release its Appendix 4C and quarterly activity report for the three-month period ended 30 September 2021 (Q1 FY22).

### COVID-19 Rapid Antigen Tests – 20m tests secured for Australia/NZ

During Q1 FY22, sales of the Atomo COVID-19 Antigen Test for professional-use grew from less than 5,000 units in all of FY21 to in excess of 100,000 units in Q1 FY22, reflecting a significant change in the rapid testing landscape in Australia. Atomo sold-out of its stock on hand, with sales during the quarter limited due to stock availability prior to a significant quantity of product arriving into Australia mid-September.

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<sup>1</sup> COVID-19 rapid testing detects SARS-COV-2, the virus that causes COVID-19

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Adoption of rapid antigen testing in Australia has been widespread, with Atomo acquiring more than 70 customers across a broad range of industries including aged care, mining, transport & logistics, industrial, and government agencies.

Atomo announced, on 5 October 2021, a new agreement with Access Bio under which Atomo has the right to purchase up to 20m Access Bio COVID-19 Antigen Tests (10m professional-use and 10m self-tests). Under the new agreement, Atomo has the right, but not the obligation to purchase the COVID-19 Antigen Tests by 15 October 2022 and to sell the tests under Atomo branding in Australia and New Zealand (subject to, in the case of the self-test, obtaining required regulatory approvals).

Atomo also received under the new agreement with Access Bio a one-off fee of US\$1.72m (AUD\$2.4m<sup>2</sup>) replacing any payments due under Atomo's existing agreements with Access Bio. Conditional on Access Bio meeting the supply requirements in respect of the rapid antigen tests under the new agreement, the previous COVID-19 antibody test and antigen test agreements<sup>3</sup>, and the HIV test OEM agreement<sup>4</sup> between the parties will terminate.

During the quarter, Atomo commenced piloting a self-testing program in partnership with Monash House Private Hospital in Clayton, Victoria, to establish local usability and acceptability evidence for self-testing, and better inform commercial deployment in the Australian market. Atomo is actively working to have the Atomo COVID-19 Antigen Test for self-test use entered in the Australian Register of Therapeutic Goods (ARTG) and has received significant inbound interest in relation to the product, including from a number of national retail groups.

Atomo continues to see steady demand for its COVID-19 rapid antibody test in Australia.

## **HIV**

In April 2021, we announced that Viartis (through its subsidiary Mylan) and Unitaid had entered into a multi-year agreement to expand access to HIV self-testing in low and middle-income countries (**LMIC**). Under the agreement, Viartis (being one of two successful tenderers) is

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<sup>2</sup> AUD:USD 1:0.73c

<sup>3</sup> ASX release 28 July 2020

<sup>4</sup> HIV agreement signed 22 December 2017 relating to Access Bio commercialising its own HIV professional use test for LMIC global health markets



supplying the *Mylan HIV Self-Test*, which is designed and manufactured by Atomo, to 135 LMIC countries.

Atomo received an initial order from Viatris of 250,000 Atomo manufactured HIV Self-Tests late in Q4 FY21, for supply into the South African market. First shipments commenced at the end of Q4 FY21, with the remainder of the order delivered in Q1 FY22. A number of subsequent orders from Viatris were received during Q1 FY22 for delivery to India and two other countries, along with additional orders from Atomo's European distributor Owen Mumford who is currently expanding its geographic reach into Eastern European markets, which continue to see high levels of HIV infection and undiagnosed populations.

### **US Market**

Atomo has commenced a recruitment process for key business positions, including a number in the US to support market development efforts.

Atomo was pleased to welcome Deborah Neff to its board of directors during Q1. Deborah is based on the US West Coast and has extensive experience in the US diagnostics market.

### **New Product Development**

Atomo continues to invest in the development of new rapid test solutions supporting a broadening of the addressable target markets including rapid diagnostics solutions for a range of non-blood samples including solutions for nasal swab and saliva based testing.

### **Financials**

Cash receipts from customers in Q1 FY22 totalled \$2.2m, significantly up on the prior quarter (\$717k, Q4 FY21). This was due to the collection of a number of customer receipts early in the period relating to Q4 FY21 HIV and OEM sales, and growth in sales of the Atomo COVID-19 Antigen Test during the quarter.

Sales in Q1 FY22 (unaudited) were approximately \$2.4m, up 260% on the prior quarter revenue (\$670k, Q4 FY21).

Ongoing investment continued in R&D and the final phase build of the next generation blister machine. Working capital was committed to restocking Atomo COVID-19 Antigen Tests.

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In accordance with ASX Listing Rule 4.7B, Atomo advises that an amount of \$271k was paid during the quarter to Atomo Directors in salary and directors' fees.

Atomo's cash balance at the end of the quarter declined to \$15.2m with expenditure on PPE, R&D and working capital, partially offset by strong customer receipts.

As part of the new supply agreement between Atomo and Access Bio, a one-off payment to Atomo of US\$1.72m (AUD\$2.4m<sup>5</sup>) was agreed and paid in early Q2 FY22.

### **Key Priorities**

Atomo's key priorities for FY22 include:

- Capitalising on local COVID-19 opportunities, including launch of the COVID-19 Antigen Test for self-test use (subject to TGA approval) and increasing resources to support growing demand across public health and private sector channels.
- Growing Atomo's HIV business globally, through the support of key partners, and expanded commercial activity domestically.
- Increasing Atomo's commercial and business partnership resources and capabilities, including in the US.
- Continuing to explore strategic partnership opportunities with companies looking to improve the usability and marketability of their existing point-of-care testing products.
- Ongoing development of non-blood rapid test solutions to expand Atomo's addressable market.

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.

An online briefing will be provided at **3.00pm (Sydney time) on Tuesday, 26 October 2021**.

Participants can pre-register ahead of time via the following link:

[https://us02web.zoom.us/webinar/register/WN\\_NxeYdQjIRtOisOliFfM1fA](https://us02web.zoom.us/webinar/register/WN_NxeYdQjIRtOisOliFfM1fA)

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<sup>5</sup> AUD:USD 1:0.73c



Once the registration form is completed, investors will receive a confirmation email with details on how to access the briefing. If you would like to ask a question during the briefing, please send your question ahead of the session to: [george.kopsiaftis@irdepartment.com.au](mailto:george.kopsiaftis@irdepartment.com.au)

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*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, HIV, viral vs bacterial differentiation and female health. See more at [www.atomodiagnostics.com](http://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 (A\$'000)	Actual Funds Deployed		Ref
		Actual Accumulated (A\$'000)	As a % of Prospectus %	
Expansion of Manufacturing & Distribution	11,700	4,508	38.5%	1
Research & Development and Product Commercialisation	11,025	4,468	40.5%	2
GHIF Loan Repayment (Including Outstanding Interest)	7,010	7,746	110.5%	3
Administrative Costs	2,446	1,158	47.3%	4
Market Expansion	1,600	867	54.2%	5
Interest on Convertible Notes	900	756	84.0%	6
Working Capital & Operating Costs	5,055	3,305	65.4%	7
Costs of the Offer	2,704	1,897	70.2%	8
<b>TOTAL (INCLUDING EXISTING CASH)</b>	<b>42,440</b>	<b>24,706</b>	<b>58.2%</b>	<b>9</b>

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