



ASX Announcement

27 January 2023

## Quarterly Activity Report Q2 FY23

### Highlights

- **Cash receipts:** Cash receipts of \$1.65m during the quarter, made up of \$442k in receipts from customers and \$1.2m received from Government R&D Tax rebate and EMDG sources. H1 cash receipts of \$3.0m.
- **Revenue:** \$482k in (unaudited) Q2 FY23 revenue during the quarter, mostly driven by HIV sales. Product Sales Revenue for H1 FY23 of \$1.4m.
- **HIV:** 109k tests sold across global markets during the quarter with a further order for another 100k tests received in early Q3 FY23. Total HIV units ordered to date in FY23 of 302k. Distribution agreement signed with Australian Pharmaceuticals Industries (API) for supply into the local pharmacy channel.
- **Agreement for a unique pregnancy test:** new deal executed with NG Biotech to accelerate OEM sales of the Pascal device used by NG in its blood based hCG pregnancy test. Atomo secures exclusive distribution rights for the product in Australia & New Zealand, Canada and the US. NG submits further order for another 107k Pascal devices
- **Usability study:** Completion of an independent Australian study demonstrates overwhelming performance improvements and very high user preference for the Pascal test platform when compared with a leading CE Marked rapid blood based self-test
- Atomo finished the quarter debt-free and with **cash on hand of \$10.2m**

**SYDNEY Australia, 27 January 2023** – Atomo Diagnostics Limited (ASX: AT1) (**Atomo**) is pleased to release its Appendix 4C and quarterly activity report for the three-months ended 31 December 2022 (Q2 FY23).



## **HIV Tests**

During Q2 FY23, Atomo sold 109k HIV self-tests, with a further order for another 100k tests received in early Q3 FY23. Total HIV tests ordered to date in FY23 exceeds 302k.

In Australia, the company continued to expand its footprint in the pharmacy sector, including through the execution of an agreement for sale and distribution with Australian Pharmaceuticals Industries (API), one of Australia's leading wholesale distribution companies to the pharmacy sector. Extensive business development activities continued throughout Q2 FY23 with brand awareness campaigns across a number of festivals and media, and planned activity in Q3 FY23 in conjunction with the World Pride Festival to be held in Sydney in late February and early March.

Atomo is now engaging with key stakeholders and government to advocate and propose public health support and funding for availability of HIV Self-Tests in the community to expand access beyond the current user pays channel in Australia, including initiation of a media programme to support expanded public health testing at a national policy level. Australian public authorities providing such support would align with recent changes in the UK and US.

## **Blood Based Pregnancy Testing**

Atomo signed a new agreement with its long-term partner NG Biotech covering the manufacture and distribution of unique rapid blood-based pregnancy tests for professional use and at-home self-test use in key global markets. Under the agreement Atomo has secured exclusive distribution rights for both professional and self-test versions of the product in Australia, New Zealand, Canada and the United States. These tests have CE Mark and the company announced earlier in FY23 that NG Biotech had recommenced ordering Pascal devices in support of product expansion in Europe and launch in Brazil. Early in Q3 FY23, NG Biotech ordered a further 107k Pascal devices, bringing total orders to date for FY23 to 247k units.

It is acknowledged that detectable hCG levels typically build up quicker in blood than in urine, making the test potentially suited to early detection of pregnancy and the company has received interest from potential channel partners, with earlier detection of pregnancy seen as a real competitive advantage when compared with more common urine rapid tests.



The company is prioritising registration and launch of the tests in Australia and New Zealand, working with NG Biotech to complete planning for US product registration activities and engaging with various potential channel partners specifically for the US market.

### **Usability study**

An independent study was conducted by an experienced Australian human factors consultancy firm during Q2 FY23 to validate Atomo's Pascal device in the hands of untrained users. The untrained Australian users carried out blood based self-test procedures with the Atomo Pascal device and with a leading CE Marked self-test, commercialised and supplied widely in Europe. The study found that the Pascal device dramatically improved the ability for consumers to reliably complete the correct test workflow and follow steps correctly. Additionally, the study confirmed an overwhelming preference for Pascal over the multi-component kit with more than 90% of study participants choosing Pascal. Findings from the study demonstrating:

- **Greater than 90% reduction in incorrect blood delivery errors** - Pascal reduces blood delivery errors from 48% down to 4% among first time untrained users
- **100% reduction in buffer delivery errors** – An error rate of 16% seen with the alternative test kit format compared with a zero error rate with the Pascal device
- **Easier to use and overwhelmingly preferred by users** – more than 90% of participants indicated that they prefer using the Pascal platform over the multi component kit
- **40% reduction in time to perform the test procedure** - participants using Pascal completed their test steps in 60% the time taken with the multi component test kit **(3mins quicker per test with Pascal)**

Atomo firmly believes that the unique ease of use and reliability of its Pascal cassette for blood testing increases the potential for Atomo to be successful in securing rapid test approvals that enable entry into key growing CLIA-waived professional use settings and for supply over the counter and online.



The company will be exhibiting its unique test solutions at two international conferences in February, where the proven market leading performance of Pascal will support engagement and new customer acquisition:

- Arab Health: Dubai, (Jan 30 – Feb 2) <https://www.arabhealthonline.com/en/Home.html>
- Medical Design and Manufacturing (MD&M West): Anaheim, US, (Feb 7 – 9)  
<https://www.imengineeringwest.com/en/show-brands/mdm-west.html>

## **Financials**

Total cash receipts from customers for Q2 FY23 of \$442k, with \$309k in receipts from the sale of HIV self-tests, \$87k from OEM sales and \$46k from COVID-19 rapid antigen test sales. Cash receipts from customers in H1 FY23 totalled \$1.8m. Total revenue (unaudited) of \$482k for Q2 FY23, predominantly from HIV sales, resulted in H1 FY23 revenue of \$1.4m. During the period Atomo received a further \$1.2m in cash which primarily related to the Government R&D tax rebate for the FY22 year, and a small additional component relating to the receipt of Export Marketing and Development Grant funding.

At the end of Q2 FY23, Atomo had \$10.2m in cash on hand and remains debt-free. The company continues to focus on targeted, considered expenditure and cash management as it moves into the second half of FY23 and notes that capital expenditure related to the manufacture of its platforms and finished tests is now essentially complete.

In accordance with ASX Listing Rule 4.7C.3, Atomo advises that an amount of \$210k was paid during the quarter to Atomo Directors in salary and director's fees.



## **Key Priorities**

Atomo's key priorities for H2 FY23 include:

- Growing HIV sales domestically in Australia including a focus on the public health market, and internationally through its distributors, with the planned addition of new distributors for HIV professional use testing and HIV self-testing
- Prioritising registration and commercialisation activities in relation to the Atomo hCG pregnancy professional use and at-home self-test products, in markets where Atomo has now secured exclusive distribution rights
- Continuing to expand Atomo's OEM technologies, including using the favourable results from the recent Pascal usability study
- Assessing opportunities to use the company's existing IP, technologies and capabilities in adjunct markets such as securing contracts to supply custom reagent blisters to the IVD market (with a focus on higher value micro-fluidic and rapid molecular segments)

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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