



ASX Announcement

27 April 2023

Quarterly Activity Report Q3 FY23

Highlights

- **Cash receipts:** Cash receipts from customers during the quarter of \$1.1m, with \$864k related to HIV sales and 248k related to OEM sales.
- **Revenue:** \$598k (unaudited) in Q3 FY23 revenue during the quarter, mostly driven by HIV sales.
- **HIV Self-Test:** Sold more than 100k self-tests during the quarter. Take or pay contract for South Africa domestic market worth \$1.9m signed with a first purchase order received and a European consumer health customer secured with a \$900k purchase order received during the quarter. Month on month sales growth in Australia across the quarter as awareness and sales campaign continues and more pharmacies start to stock the product.
- **Pregnancy Self-Test:** blood based hCG pregnancy test submitted by Atomo to the Australian TGA for review. Work underway to determine pathway for US FDA submission. Additional purchase order for 107k Pascal cassettes received from NG Biotech (NGB) during the quarter for finished product in markets where the product is already approved and supplied by NGB.
- **IP Update:** Atomo's patent related to the design and manufacture of its novel blister reagent functionality was granted in the both the US and China during the quarter, representing further valuable Intellectual Property (IP) protection for the company's unique easy to use rapid test solutions in the world's two largest healthcare markets.
- Atomo finished the quarter debt-free and with **cash on hand of \$8.9m**

SYDNEY Australia, 27 April 2023 – Atomo Diagnostics Limited (ASX: AT1) (**Atomo**) is pleased to release its Appendix 4C and quarterly activity report for the three-months ended 31 March 2023 (Q3 FY23).



HIV Self-Tests

During Q3 FY23, Atomo sold more than 100k HIV self-tests across Australia and LMIC markets, and received an initial purchase order worth approximately \$900k from UK based consumer testing focussed distributor Newfoundland Diagnostics.

Atomo continues to add new pharmacy customers to the local domestic channel following successful campaigns around World Pride, Sydney Mardi Gras events and exhibiting at Australia's leading Pharmacy Expo (APP2023). Engagement continues with various state Departments of Health, which led to an initial sale to the WA Department of Health. Atomo has also been in discussions with the Federal Government in relation to potential broader Government backed screening programmes, with a meeting recently held in Canberra to discuss broader HIV Self-Testing policy adoption.

During the quarter, Atomo expanded its relationship with Viatris, Inc with the execution of a binding take or pay contract worth \$1.9m over 5 years for the South African domestic market. An initial purchase order for that market has been received from Viatris. There is a continued push for further uptake in global health LMIC markets, including representation by Viatris at the G20 Global Health Working Group in Goa, India at which the emphasis was on the prioritisation of access to diagnostics, and the need for decentralised and regional manufacture and distribution within global health markets. Atomo, with its WHO certified production facility for HIV Self-Tests located in Cape Town, South Africa, is well positioned to respond to this priority need in global health diagnostics.

Blood Based Pregnancy Testing

Following the execution in Q2 FY23 of a new manufacture and distribution agreement with long-term partner NG Biotech for global expansion of a unique rapid blood-based pregnancy test already commercialised in France, Atomo and NG have been working together to progress regulatory approvals in the territories for which Atomo has the distribution rights. As a priority, a submission was made to the TGA for registration of the test during Q3 FY23. Subject to receiving approval from the TGA, Atomo will commence supply into the Australian market and seek commercial channel partners in other regional markets, with New Zealand, Singapore, Korea and Vietnam the next priority.



Atomo has been working with a regulatory advisor in the US market with highly relevant recent experience in FDA engagements to assist in the preparation and planning for an FDA submission, with further clarity on the pathway and timing expected during Q4 FY23.

Business Development

Following the successful Usability Study conducted during Q2 FY23 demonstrating the significant reduction in common user errors and recent progress expanding the scope of Atomo's finished product distribution relationships, Atomo has continued to engage during Q3 FY23 with the market in relation to its unique test solutions including exhibiting at Arab Health in Dubai and Medical Design and Manufacturing in the US.

In Australia, Atomo exhibited at the Australia Pharmacy Professional conference and exhibition to promote its HIV Self-Test and to undertake preliminary market engagement in relation to the blood-based pregnancy test, anticipated to be released in CY23 (subject to TGA approval). Market soundings were also undertaken in relation to other tests of interest from retail and health care professionals.

These exhibitions have created a number of leads and opportunities, continued to build awareness of Atomo's IP protected technology and product offerings, and reaffirmed the market is continuing to seek unique and differentiated consumer testing solutions to drive growth beyond the COVID-19 pandemic.

IP Update

The US Patent and Trademark office issued a patent on April 25 2023 related to the design and processes to manufacture Atomo's integrated reagent blister - US patent No 1163733. The Chinese equivalent patent CN 113650956 was granted on March 31 2023. This latest US patent is in addition to existing US patents 9295987 and 10525463 relating to an integrated test system that includes a reagent blister functionality in a test device.

Untrained users often struggle to properly deliver the correct volume of reagent from dropper bottles commonly used in standard tests kits. This is known to be one of the common sources of diagnostic error with test kits, that have to date limited the approval of these types of tests



kits for self-test use in the US, outside of COVID. By contrast, a recent independent Australian usability evaluation demonstrated that Atomo's integrated buffer delivery system completely removes this error completely, reducing the error rate from 16% with a standard dropper bottle down to zero with the Atomo solution.

Atomo's focus on developing tests with inherent ease of use is underpinned by innovative, engineered solutions and the award of these patents is further recognition of the novel nature of the technology. Importantly, usability is a critical factor considered by regulators when assessing the scope of rapid tests approvals. For untrained users approvals are typically only granted where the opportunity for users to make errors has been eliminated or significantly reduced. It is for this reason that Atomo has been able to achieve self-test approvals for both Galileo and Pascal in multiple jurisdictions, and why there is continued focus on this differentiating functionality.

Financials

Total cash receipts from customers for Q2 FY23 of \$1.1m, with \$864k in receipts from the sale of HIV self-tests and \$248k from OEM sales. Total revenue (unaudited) of \$598k for Q3 FY23, predominantly from HIV sales.

At the end of Q3 FY23, Atomo had \$8.9m in cash on hand and remains debt-free. The company maintains a clear prioritisation of spending on activities that are expected to maximise the opportunity for returns on its substantial installed manufacturing asset base and intellectual property portfolio, including focusing on regulatory approvals and registrations for new and existing products, and on building out its pipeline of new business opportunities.

In accordance with ASX Listing Rule 4.7C.3, Atomo advises that an amount of \$207k was paid during the quarter to Atomo Directors in salary and director's fees.

Key Priorities

Atomo's key priorities for the remainder of FY23 and the first half of FY24 include:

- Commercialisation planning for the next Atomo finished product rapid tests beyond HIV and pregnancy



- Completing an ongoing restructure of the company's HIV distribution arrangements to better support continued revenue growth, including an expansion into new markets
- Expanding distribution arrangements with key channel partners to include commitments to launch other Atomo finished products
- Securing a number of device reseller agreements to support the promotion and scale up of Atomo's OEM supply business through the activities of test strip development companies that have direct access to the market for new tests being commercialised

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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.

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