



ASX Announcement

29 January 2024

Quarterly Activity Report Q2 FY24

Highlights

- **Strong growth in revenue and margins across Atomo's HIV Self-Test business:**
 - Over 130k units sold during the quarter, primarily into high value developed markets in Europe and Australia.
 - HIV Self-Test successfully launched across TESCO supermarkets in the UK and launching in pharmacies across Germany.
 - Order received from UK partner Newfoundland for an additional 220k units to support product expansion in the UK and Germany and launch into new European markets.
 - Significant Australian revenue growth in December following the formal adoption of HIV Self-Testing into government policy on World AIDS Day.
- **Re-emerging POC Technology (OEM) demand post COVID:**
 - Over 50k units sold during the period to existing customers, with a further order over 50k units received in January.
 - Increased inbound enquiries for Atomo products and technology post US FDA 510k approval for Pascal and traction in OTC channels earlier in FY24.
 - An inaugural purchase order received recently from a global diagnostic company relating to assessment of Atomo cassettes for potential use with a diagnostic reader system.
- **Continued progress with Pregnancy Testing:**
 - Atomo and NG Biotech (NGB) have progressed generating additional data requested by TGA, with a response to TGA imminent.



- NGB secured a significant contract covering Italy, Spain and Portugal with multinational TOWA Pharmaceutical.
- Atomo and NGB held a pre-sub meeting with US FDA in December and are now updating clinical plans to support US product approvals.
- **Revenue:** \$710k (unaudited) in Q2 FY24 revenue during the quarter, making product sales revenue for H1 FY24 of \$1.9m, compared with product revenues of \$1m (excluding COVID) for H1 FY23, representing half year over half year growth of 98%.
- **Cash receipts:** Cash receipts of \$1.9m during the quarter, made up of \$1.1m in receipts from customers and \$761k received from Government R&D rebate. H1 cash receipts of \$2.8m. Atomo finished the quarter debt-free, with **cash on hand at quarter-end of \$6.5m.**

SYDNEY Australia, 29 January 2024 – Atomo Diagnostics Limited (ASX: AT1) (**Atomo**) is pleased to release its Appendix 4C and quarterly activity report for the three-months ended 31 December 2024 (Q2 FY24).

HIV Self-Test

Newfoundland Diagnostics took delivery of the remaining shipment of their initial order for the UK and European markets and launched the product in Tesco, the largest supermarket chain in the UK. A launch campaign is now underway across the UK to raise awareness about HIV in general and the availability of the Newfoundland HIV Self-Test in particular, with further UK national media anticipated to coincide with UK National HIV Testing Week in February.

December saw the launch of the HIV Self-Test in Germany through pharmacy chain MePro FH-Handels GmbH, with display stands now in pharmacies across the country. Further expansion into other retail outlets and across other markets in the EU will roll out in 2024.

To support continued growth in the European market, Newfoundland placed an order for an additional 220k tests, with the first tranche of 50k units under manufacture. As a result of meeting their volume obligations for CY2024, the contract with Newfoundland remains exclusive and will be extended for a further five years.



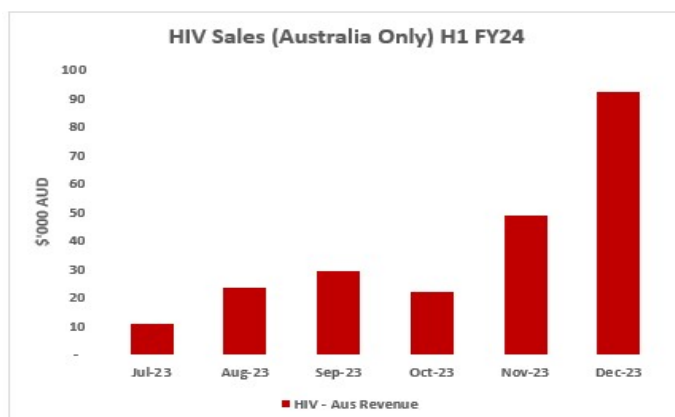
During the period, Atomo assisted Newfoundland to submit for registration with the Colombian regulator, with approval anticipated in the coming months. In parallel, Newfoundland have opened the world's first retail store dedicated solely to rapid self-testing in Bogota, Colombia.



Newfoundland's new innovative consumer self-test store in Bogota, Colombia

In Australia, Atomo has been working with NAPWHA and Grindr to promote awareness and access to HIV Self-Tests. Atomo also continues to support existing vending machine programs as well as working with State governments implementing larger vending machine programs in the coming months. Vending machine roll out to a wider public audience allows further grass roots awareness of our brand and product, so anchoring possible interest in other test products as these become available in Australia.

As the graph below shows, HIV sales continue to grow strongly in the Australian market, with recent policy changes that went into effect 1st December driving government adoption of self-testing policy and delivering immediate growth in December sales, with continued growth is anticipated over the coming year.





Engagement with State and Federal Governments is accelerating post this policy change, suggesting the potential for broader adoption of HIV Self-Testing across public health channels during 2024 and beyond.

POC Technology (OEM)

Atomo sold over 50k units during the period to existing customers, with a further order over 50k units received in January. The company anticipates regular ordering from its two existing customers as they continue to focus on the commercial rollout of their blood tests post COVID.

The company has seen an increase in inbound enquiries for Atomo products and technology post US FDA 510k approval for Pascal and evidenced traction in OTC channels earlier in FY24. This combined with demonstrated overwhelming user preference and error reduction in independent evaluations provides a compelling value proposition to industry players increasingly focused on the transition to decentralised testing.

Atomo has collaborations now in place with new diagnostic companies interested in accessing Atomo technology, having recently received a purchase order relating to assessment of its Elion cassette for use with a reader system. The company also anticipates executing agreements in the coming months with two Australian entities related to Atomo devices supporting commercialisation of a blood-based rapid test and a swab based rapid test.

Blood Based Pregnancy Testing

Atomo received a detailed response from the TGA relating to the application to register professional use and self-test variants of the Atomo blood pregnancy test in Australia. Atomo and NG Biotech (NGB) have progressed generating additional data requested by TGA, with a response to TGA imminent. The company remains hopeful that both versions of the product will receive regulatory approval for Australia and be launched nationally during 2024.

NGB secured a strategic partnership agreement with multinational TOWA Pharmaceutical covering NGB's version of the Pascal based blood pregnancy self-test.

Atomo and NGB participated in a pre-sub meeting with US FDA in December with a follow-up meeting with FDA is scheduled for early March.



Financials

Total revenue (unaudited) of \$710k for Q2 FY24, comprising \$624k for HIV sales, and OEM sales of \$86k, bringing total revenue for the half year FY24 to approximately \$1.9m.

HIV revenues increased during the period with expectations of growth to continue into H2 FY24 for reasons noted above. The increasing mix of HIV sales in developed healthcare markets with better pricing when compared to Atomo's traditional global health channels is reflected in improving gross margin. Overall GM for the company improved to 46% when compared to 39% (excl'd Covid) for the corresponding period in H1 FY23.

Cash receipts from customers during the quarter were \$1.1m with a further \$761k received from the Government R&D rebate program. Atomo finished the quarter debt-free and with **cash on hand of \$6.5m.**

In accordance with ASX Listing Rule 4.7C.3, Atomo advises that an amount of \$208k was paid during the quarter to Atomo Directors in salary and director's fees.

Key Priorities and Use of Funds

- Continued growth of HIV sales in Australia with a focus on scaling emergent public health funded programs and an expansion of global HIV commercial relationships.
- Secure new OEM customers for Pascal following FDA approval, in addition to executing agreements with partners related to other Atomo platforms.
- Continued market engagement through active attendance at key conferences and events focusing on new test development and commercialisation.
- Securing regulatory approval and launch in Australia for Atomo's pregnancy tests, and completion of FDA submission plans and a go-to-market strategy.



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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.