



ASX Announcement

26 October 2023

Quarterly Activity Report Q1 FY24

Highlights

- **HIV Self-Test:** Sales of 176k units during the quarter, primarily driven by delivery of product to Newfoundland Diagnostics for the UK and European markets, with the majority of their initial order being delivered and product now stocking the shelves of Tesco nationwide across the UK. Additional distribution territory of Colombia contracted to Newfoundland as it seeks to roll out further into other global markets, with a first purchase order for 30k units placed to support market entry. An initial order from Viatrix for delivery to an African Ministry of Health, with further ordering expected through FY24.
- **Pregnancy Self-Test:** NG Biotech continues to seek opportunities for growth in the European market. Having submitted to the Australian TGA in FY23, Atomo continues to wait for TGA approval with a response expected shortly. US regulatory preparation continues, with a pre-submission application made to FDA this quarter.
- **POC Technology (OEM):** 151k Pascal units sold during the period as NG Biotech and Lumos continue to restock and expand territories, with discussions with new potential partners apparently progressing well.
- **Revenue:** \$1.21m (unaudited) in Q1 FY24 revenue during the quarter, significantly up compared with Q4 FY23 (\$583k), with \$892k for HIV sales and \$321k OEM sales.
- **Cash receipts:** Cash receipts from customers during the quarter of \$841k. Atomo finished the quarter debt-free, with **cash on hand at quarter-end of \$6.9m**, with an ATO rebate payment of \$761,000 for R&D investment received post quarter-end.

SYDNEY Australia, 26 October 2023 – Atomo Diagnostics Limited (ASX: AT1) (**Atomo**) is pleased to release its Appendix 4C and quarterly activity report for the three-months ended 30 September 2023 (Q1 FY23).



HIV Self-Test

Sales of 176k units during the quarter, primarily driven by delivery of product to Newfoundland Diagnostics for the UK and European markets, with 75% of their initial order being delivered during the quarter to support product stocking / launch across Tesco's 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.

Further, and in recognition of the strong and building relationship between Atomo and Newfoundland, the parties have amended their supply and distribution agreement to include the territory of Colombia to support Newfoundland's efforts to roll out further into other global markets. An initial purchase order for 30k units is expected to be placed to support market entry. Further territories under active discussion.

In Australia, sales continue to clinics and pharmacies, with emerging engagement with State and Federal Governments suggesting the potential for broader adoption of HIV Self-Testing within public health channels. NAPWHA (National Association of People with HIV Australia) recently launched a program to distribute up to 12,000 free Atomo HIV Self Tests to communities that are either over-represented in new (or late) diagnoses OR under-represented in testing data across Australia. Additionally, NSW Health is commencing a vending machine program during FY24 in an effort to reach a broader range of testing candidates that are not currently seeking clinic and mainstream testing services.

An initial order of 52k units was received from Viatrix for delivery to an African Ministry of Health with further ordering anticipated throughout FY24 to support a tender for that country.

Blood Based Pregnancy Testing

Having submitted to TGA in Q3 FY23, Atomo awaits TGA registration of the AtomoNOW hCG blood-based pregnancy test. A substantive response from TGA is due and the company is hopeful that the product can secure approval in the coming months. Significant market interest is emerging and market research suggests that approximately one quarter of women in the pregnancy test market are keen to utilise a home blood test that delivers better early phase accuracy in detecting pregnancy.



Preparation is under way for launch of the product in Australia, subject to receipt of the TGA approval. This planning includes the appointment of an experienced pharmacy sales agency with a successful track record bringing innovative products to the Australian pharmacy retail market, to assist with launch, and drive ongoing sales efforts across the network of pharmacies nationwide. Atomo continues to seek commercial channel partners in other regional markets, with New Zealand and a number of other Asian markets the next priority.

US regulatory preparation continues, with a pre-submission meeting with the FDA scheduled later in Q2 FY24. This meeting will help in confirming our clinical regulatory pathway, costs and timing to support US approvals.

POC Technology

151k Pascal units were sold during the period as NG Biotech and Lumos continue to restock and scale up commercial activities in key markets. Ongoing engagement with potential technology customers and partners continues, with promotional activity and conference attendance continuing during the period, including attendance at AACC in the US in July to meet with potential channel partners and companies developing new rapid tests.

Financials

Total revenue (unaudited) of \$1.21m for Q1 FY24, comprising \$892k for HIV sales, and OEM sales of \$321k.

Q1 FY24 revenue growth when compared with Q4 FY23 (\$583k) was primarily driven by the delivery of some of the initial stocking order made by Newfoundland Diagnostics during the period. The remaining 25% of that initial order is being delivered and invoiced in Q2 FY24.

Cash receipts from customers during the quarter were \$841k. Atomo finished the quarter debt-free and with cash on hand of \$6.92m. Since the end of the quarter Atomo received an ATO rebate payment of \$761,000 for R&D investment made during FY23.

In accordance with ASX Listing Rule 4.7C.3, Atomo advises that an amount of \$287k was paid during the quarter to Atomo Directors in salary and director's fees.



Key Priorities and Use of Funds

Atomo's key priorities for the coming months are as follows:

- Continued growth of HIV business, including commencement of public health procurement programs
- Regulatory and commercial launch activities related to the AtomoNOW hCG ultra-early pregnancy test in Australia and New Zealand, and completion of pre-sub activity with the US FDA to enable finalisation of FDA submission plans and a go-to-market strategy.
- Finish clinical studies for the AtomoNOW Ferritin test to enable completion of a product dossier to support regulatory submission to TGA and for CE Mark under IVDR.
- Secure new OEM customers (proof of concept programs) for Pascal with a view to entering supply contracts during 2024.
- Continued market engagement through active attendance at key conferences and events focusing on new test development and commercialisation.

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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.atomodiagnosics.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.