



ASX Announcement

27 July 2023

Quarterly Activity Report Q4 FY23

Highlights

- **HIV Self-Test:** Continued sales in global health markets and sales growth in Australia (HIV sales of 75k units). Regulatory approval in Europe and UK obtained for the Newfoundland branded version of the Atomo HIV self-test late in the quarter, with sales worth ~\$900k under production for delivery in Q1 FY24
- **POC Technology (OEM):** 107k Pascal units sold during the period to NG Biotech. Purchase orders for a further 150k units from NG Biotech and Lumos Diagnostics – now under production for delivery in Q1 FY24. New OEM partner referral agreements signed to support commercialisation efforts for new tests on Atomo platforms
- **FDA Clearance for FebriDx:** 510(k) clearance obtained post-quarter end by Lumos Diagnostics for its FebriDx test which uses the Atomo Pascal platform. FDA clearance opens up predicate pathways for registration of other blood testing applications on Pascal and significantly enhances Atomo's OEM offering in the US
- **Pregnancy Self-Test:** with additional funding from capital raising, opportunity to accelerate registration and commercialisation of the Atomo blood based hCG pregnancy test across multiple geographies, starting with Australia and New Zealand, to be followed by the US. Atomo is awaiting TGA approval and US regulatory preparation is underway
- **Revenue:** \$583k (unaudited) in Q4 FY23 revenue during the quarter, \$329k for HIV sales and \$254k OEM sales and FY23 revenue of \$2.6m, comprising \$1.56m for HIV sales, COVID-19 sales \$390k and OEM sales of \$591k
- **Capital raising:** Placement and SPP to raise up to \$4m with a minimum \$2.25m committed and announced post-quarter end, with the **SPP open until 1 August**
- **Cash receipts:** Cash receipts from customers during the quarter of \$383k. Atomo finished the quarter debt-free, with cash receipts from customers over FY23 totalling \$3.3m, and **cash on hand at year-end of \$6.5m** before proceeds of capital raising



SYDNEY Australia, 20 July 2023 – Atomo Diagnostics Limited (ASX: AT1) (**Atomo**) is pleased to release its Appendix 4C and quarterly activity report for the three-months ended 30 June 2023 (Q4 FY23).

HIV Self-Test Momentum

Regulatory approval for Europe and the UK was obtained for the Newfoundland Diagnostics branded version of the Atomo HIV self-test late in the quarter, with sales worth ~\$900k under production for delivery in Q1 FY24.

Atomo continues to increase sales in Australia to the private sector through its pharmacy and online channels, as well as a number of emerging public health pilot channels. The opportunity for increased public sector HIV Self-Test screening programmes continues to be pursued with a meeting to discuss Federal Government participation held during the International Aids Society conference in July.

A large tender order is pending from an African Ministry of Health via our LMIC partner Viatris, with production and revenues anticipated in late H1 FY23.

POC Technology Business Growth

Atomo sold 107k Pascal units sold during the period to NG Biotech for their blood-based pregnancy self-test. Purchase orders for a further 150k units across both NG Biotech and Lumos Diagnostics were received signalling a resumption of business from OEM customers and refocus on non-COVID business opportunities from the diagnostics industry.

Atomo recently entered into a number of partnering agreements with leading test strip assay development companies that have direct influence on new tests coming to market. These agreements will see these partners actively promote Atomo platforms, particularly Pascal, to their extensive networks. Key points of interest to potential partners are the recent 510(k) approval for the FebriDx test on the Atomo Pascal platform and the 'best in market' usability performance achieved in the study conducted earlier in FY23.

As rapid test diagnostics continue to expand, particularly into new consumer at-home markets, usability is seen as a critical factor by regulators when assessing the range of



possible settings in which to allow rapid tests to be used, and with consumers wanting to use products offering simplicity and reliability.

Recent attendance at the American Association for Clinical Chemistry (AACC) Conference, which is the premier conference for the diagnostics industry globally, has confirmed the growing importance of products that meet the needs of regulators, clinicians and users and suggests a growing pipeline for both Atomo finished products, such as HIV and pregnancy, as well as Atomo platforms for supply on an OEM basis.

Blood Based Pregnancy Testing

Atomo awaits TGA registration of the Atomo hCG blood-based pregnancy test as announced in Q3 FY23. Upon receipt of approval from the TGA, Atomo will commence supply into the Australian market and seek commercial channel partners in other regional markets, with New Zealand, Korea and a number of other Asian markets the next priority. A commercial launch plan for Australia is well advanced and ready to go pending approval.

Funding received from the recent capital raising activity will be deployed in support of an application to the FDA for approval of the pregnancy test in the US market. Feedback from potential commercial partners has been very positive. The 510(k) approval recently obtained by Lumos Diagnostics for their FebriDx test on the Atomo Pascal platform is expected to provide a useful predicate for Atomo bringing the hCG blood-based pregnancy test to the FDA which is also based on the Pascal platform.

Financials

Total revenue (unaudited) of \$583k for Q4 FY23, and FY23 revenue of \$2.6m, comprising \$1.56m for HIV sales, COVID-19 sales \$390k and OEM sales of \$591k.

The pipeline for Q1 FY24 underpinned by purchase orders under production for Newfoundland, NG Biotech and Lumos Diagnostics, as well as further tender participation under way from Viatriis in global health markets.

Cash receipts from customers during the quarter were \$383k. Atomo finished the quarter debt-free, with cash receipts from customers over FY23 totalling \$3.3m, and cash on hand at



year-end of \$6.5m, before the proceeds of capital raising activities which commenced post year end and closes in August.

Capital Raising – Placement and SPP

Atomo recently announced the completion of a Placement and launch of a Share Purchase Plan, targeting a raising of \$4m and with \$2.25m in binding commitments, on the following terms:

- A placement of \$1.25m to institutional and sophisticated investors at \$0.036 per share, the funds from which have already been received by Atomo
- A Share Purchase Plan (SPP) of approximately \$2.75m
- A binding commitment for a further up to \$1m SPP shortfall placement if the SPP raises less than \$1m, ensuring a minimum of \$2.25m in gross proceeds will be received across the Placement and SPP

The funds raised will top up Atomo's existing year-end cash balance and provide additional liquidity to enable the company to aggressively pursue its key priorities outlined below.

The **SPP offer remains open until 1 August 2023** to give all shareholders the opportunity to invest up to \$30,000 per holder at a price that is **the lower of:**

- \$0.036 per share; and
- A 2.5% discount to the VWAP of shares traded on the ASX during the five trading days up to the closing date of the SPP

All shareholders are encouraged to take up the opportunity to participate. The SPP Booklet and Application details can be accessed via the offer site, as follows:

SPP Offer: <https://events.miraqle.com/at1-offer/>

Any queries or questions can be directed to investorqueries@atomodiagnostics.com or ph: 1300 420 208.

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

Atomo's key priorities for FY24 are as follows:

- Continued growth of HIV product sales through increased participation in global public health tenders, targeted entry into private sector markets in Asia and the Americas, a new retail focused distribution partnership in Europe & the UK and emerging Government engagement in Australia.
- The expansion of Atomo's OEM supply business and customer base through new supply contracts for Pascal, and potentially other Atomo cassettes to diagnostic test partners. Delivered through partnerships with leading test strip assay development companies that have direct influence on new tests coming to market.
- Securing regulatory approvals and launching Atomo's new rapid test products in key markets. The two new priority products are focused on women's health, being tests for the early detection of pregnancy and for monitoring iron deficiency.

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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.