



ASX Announcement

15 November 2024

2024 Annual General Meeting – MD & CEO's Address

In accordance with ASX Listing Rule 3.13.3, Atomo Diagnostics Limited (**Atomo**) attaches the Managing Director & CEO's Address to be delivered at Atomo's 2024 Annual General Meeting.

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This announcement was authorised by the Managing Director & CEO on behalf of the Board.



ATOMO DIAGNOSTICS

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WHO IS ATOMO AND WHAT DO WE DO?

Our unique portfolio of integrated rapid tests and technologies allows people to test reliably, putting healthcare in the hands of the user

WHO IS ATOMO?

- Headquartered in Australia, with a facility in South Africa, we develop, manufacture and supply innovative rapid tests and unique test technologies for professional and self-test markets
- Our solutions increasingly recognised as delivering best-in-class usability & accuracy and facilitating self-testing approval for blood-based applications
- Proven usability in field and existing self-test approvals in several markets gives Atomo potential to be successful in CLIA waived and self-test channels in the US
- Atomo's unique solutions offer a significant growth opportunity as the market continues to shift to decentralised testing and growing interest in home testing post-pandemic

WHAT DO WE DO?

Atomo focuses on two revenue channels:

Point of Care Rapid Test Products for Infectious Disease and Female Health:

- Supply of commercialised rapid tests addressing Sexual Health and a strategic interest in Women's Health (blood pregnancy and iron deficiency)

Point of Care Test Platform Technologies:

- Integrated cassette solutions supplied to partners that want improved usability and user preferences, or seeking self-test / OTC channel access
- Custom cassettes (blood and swab based) for partners seeking improved usability for POC clip-in reader solutions



FINANCIAL PERFORMANCE FY24

AUD	FY24(\$m)	FY23(\$m)	(%)
Revenue	4.09	2.54	61%
Cost of sales	(2.48)	(1.88)	
Gross Profit	1.61	0.66	144%
Gross Margin	39%	26%	
Less COVID RAT sales		0.39	
Normalised Revenue*	4.09	2.15	90%
Normalised Gross Margin	39%	37%	
Other income	1.09	1.15	(5%)
Employee benefits expense	(4.04)	(4.85)	17%
Foreign exchanges gains/(losses)	0.03	0.11	(73%)
Research and development costs	(0.24)	(0.60)	60%
Professional fees expense	(0.63)	(0.82)	23%
Inventory obsolescence expense**	(0.17)	(1.17)	85%
Other expenses	(2.03)	(2.54)	20%
Underlying EBITDA	(4.38)	(8.06)	46%

- Excluding COVID sales, revenue increased year-on-year **(YoY) across core business by 90%**. This was predominantly made up of growth in HIV Test sales (Revenue of \$3.2m) and increased OEM Cassettes sales (Revenue of \$850k)
- With ongoing cost savings initiatives implemented across the business, OpEx for FY24 reduced \$2.73m when compared to FY23 - representing a **reduction of more than 30% YoY** in underlying business costs
- With improved sales revenues and better margins combined with a reduction in operating costs, overall EBITDA losses were nearly halved - down \$3.68m for the year compared to the prior period, **a reduction of 46% YoY**

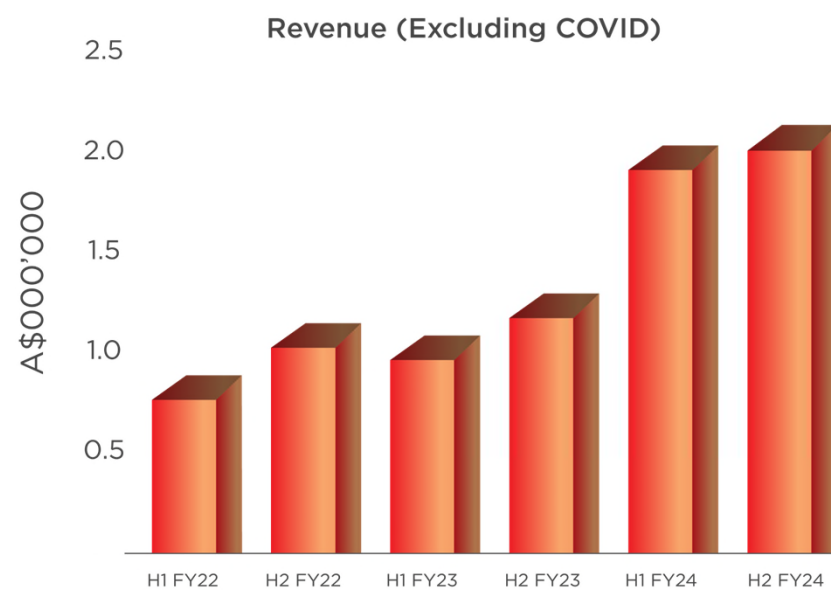
* Excluding non-recurring COVID revenue

** Prior year comparative includes \$1m COVID stock provision

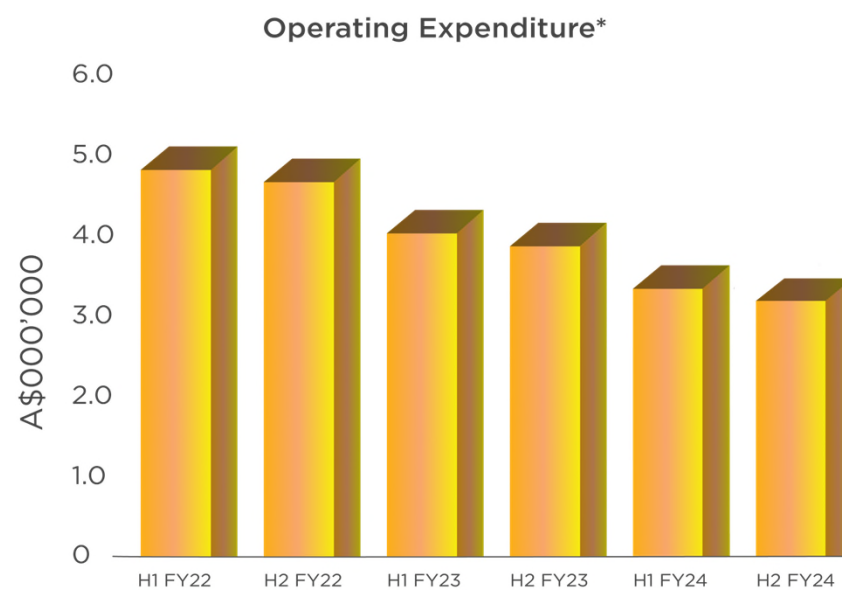


SUPPORTIVE FINANCIAL TRENDS

Well positioned for profitability with no need for significant CapEx to fund future revenue growth



Revenue, gross profit and gross profit margin all show material improvement

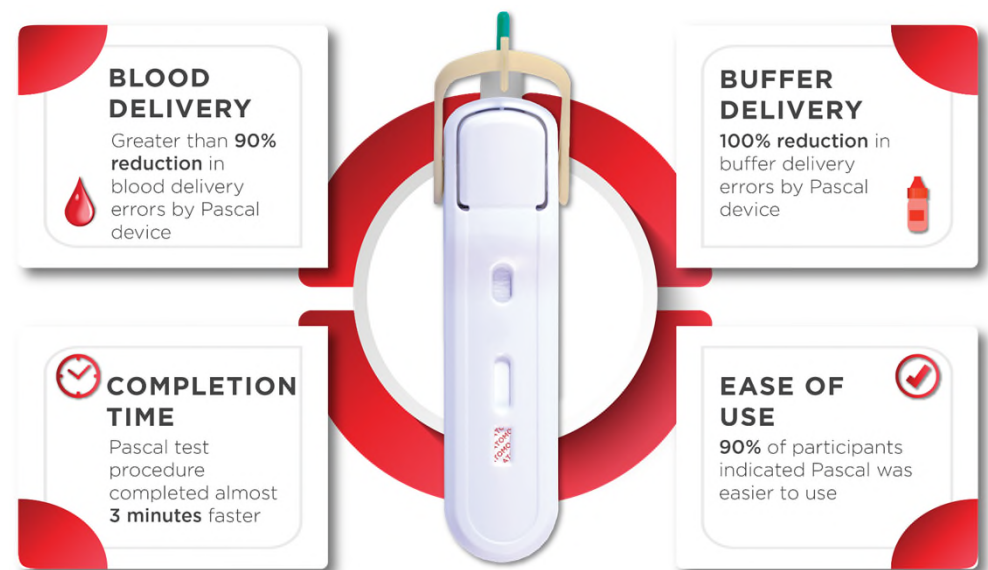


OpEx continues to reduce materially, having come down ~30% over the past two years*

*Excluding one-off impairments/stock write offs



ATOMO PLATFORM DRIVING ADOPTION OF RAPID TESTING



Report - Comparative usability analysis of two rapid diagnostic self-test kits [LINK](#)



BLOOD TESTING

Atomo's solutions offer improved performance and best in-class usability in point-of-care and self-testing

Built-In Safety Lancet

- Eliminates the risk of hazardous sharps injuries by locking the needle inside the device after use

Accurate Blood Collection and Delivery

- Blood collection unit designed to collect and deliver the correct sample volume to the test strip

Integrated Buffer Delivery

- In-built buffer storage blister allows for button activated delivery of the required quantity of buffer to the test strip

Interlocked User Steps

- Devices design forces correct sequence of user steps improving reliability and compliance



SWAB TESTING

The Atomo Curie Platform utilises Atomo's existing core IP and know-how to improve usability and performance of swab-based rapid tests

Compatible With Existing Swab-Based LF Strip Tests

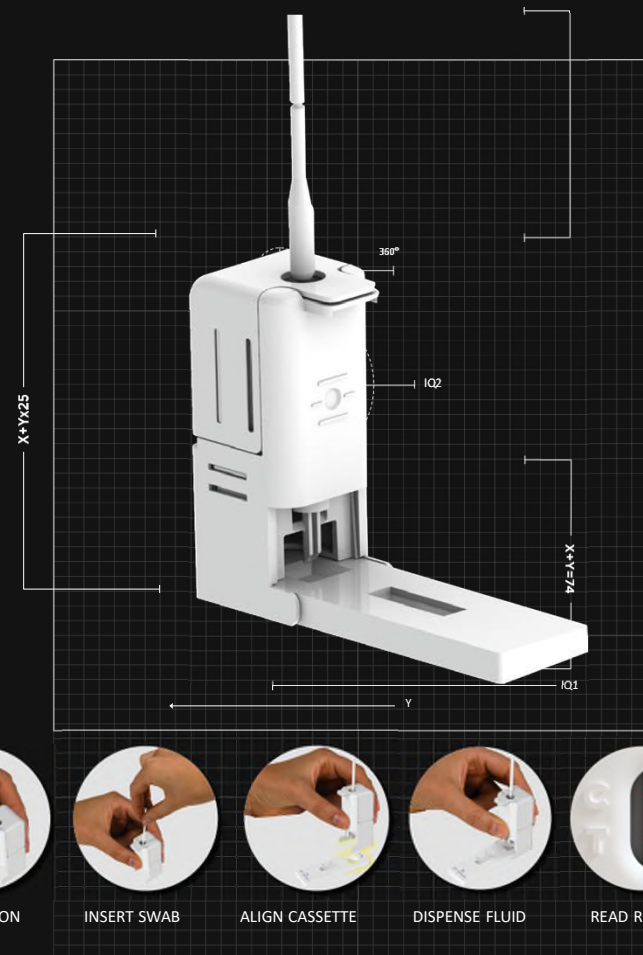
- Compatible with existing rapid test cassettes and swabs (nasal, nasopharyngeal, throat, vaginal)

Integrated Patented Blister Technology

- In-built buffer blister allows for button activated mixing of buffer and sample

Improved Sample Delivery Process

- Proprietary process and a controlled volume of buffer delivered to improve sample concentration line intensity



DIGITAL COMPATIBILITY

Atomo has developed solutions to deliver compatibility with POC reader and for at-home enabled smartphone-based testing, maximising ease of use, repeatability and accuracy of results

Reader Compatibility

- Atomo platforms are easily adapted for use in a range of POC reader formats for both traditional visual and fluorescence test readers

Atomo App

- A custom mobile application for self-test users has been developed for standard lateral flow cassettes or Atomo's Pascal cassette
- Image analysis capable of reading line intensity to provide semi-quantification of results
- Eliminates common user errors such as use of expired test and not waiting for enough time to read result
- Digital animation of steps of use further improves ease of use and performance



PRODUCT REGISTRATIONS

Product Registrations – Atomo as Listed Manufacturer

HIV Self-Test | US\$4bn (2026) [\[LINK\]](#)

- TGA | Australia
- WHO PQ | LMIC
- CE Mark | UK & Europe

COVID-19 Antibody Test (Discontinued)

- TGA | Australia

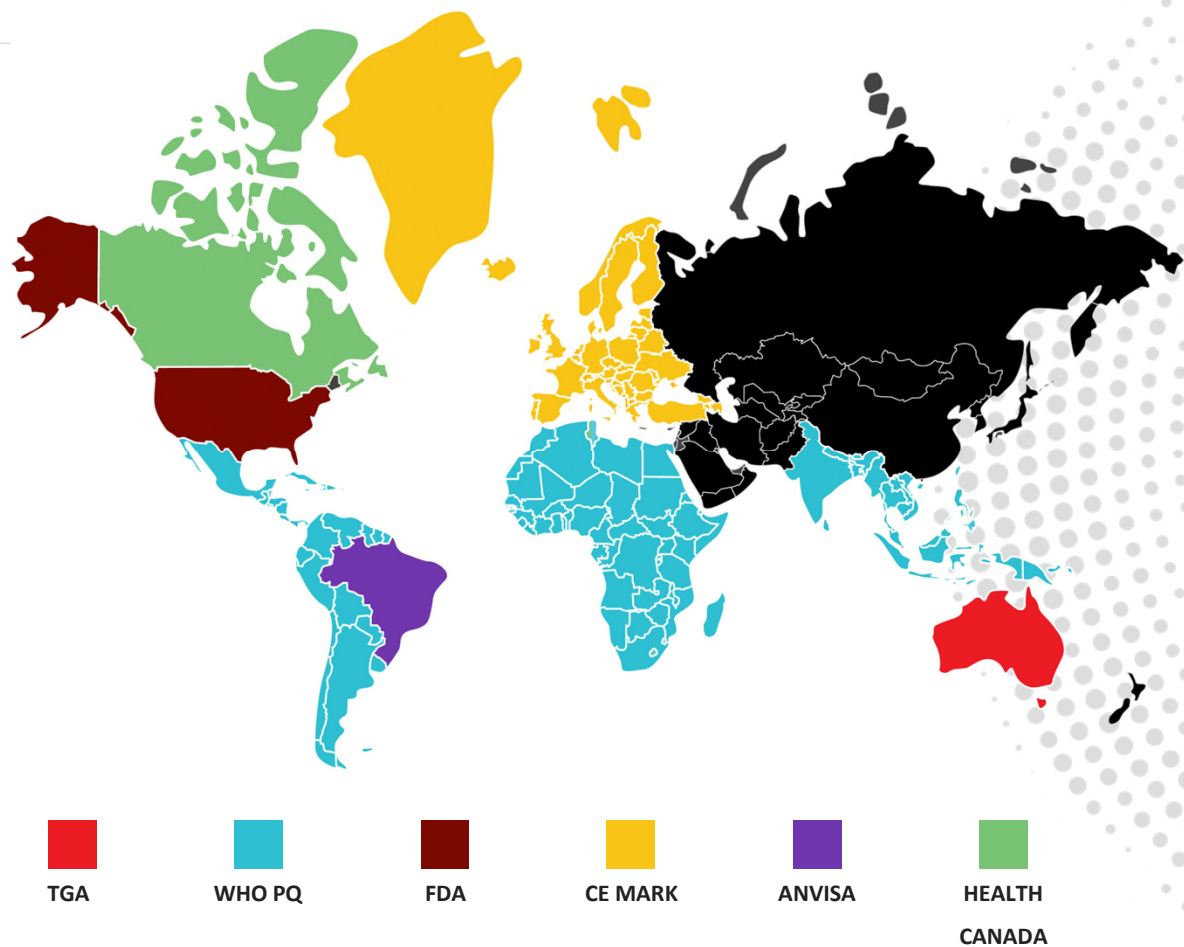
Product Registrations – Atomo Partners

Pregnancy Test | US\$2.1bn (2026) [\[LINK\]](#)

- CE Mark | UK & Europe
- ANVISA | Brazil

FebriDx | US\$5.2bn (2026) [\[LINK\]](#)

- FDA (510k) | USA
- CE Mark | UK & Europe
- TGA | Australia
- Health Canada | Canada



INTELLECTUAL PROPERTY PORTFOLIO

- **Family 1:** Diagnostic System
PCT/AU2011/000315
- **Family 2:** Sampling Assembly
PC/AU2011/001321
- **Family 3:** Fluid Control in Integrated Testing Devices
PCT/IB2014/066210
- **Family 4:** Integrated Fluid Module and Test Device
PCT/AU2016/051134
- **Family 5:** Integrated Blood Testing Device
PCT/AU2018/051114
- **Family 6:** Pre-Mix Test Vessel
PCT/AU2022/050812
- **Family 7:** Automated Verification & Guidance of Test Procedure
PCT/AU2022/051076



Proprietary automated blister manufacturing machine



ATOMO HIV SELF TEST

Achievements

- Significant investment into HIV elimination in Australia from Federal Government with ~\$44m investment into treatment and prevention strategies, including funding for HIV self-testing
- NAPWHA program expands consistently over the course of the year, with a purchase order this month for ~\$440k received to support direct promotion by Grindr
- NSW Ministry of Health launches MyTest Vending Machine program in NSW, with ~5,000 units already supplied across 30 machines state-wide; 70 machines targeted in total
- Launch in Tesco Supermarkets and Boots Pharmacies in the UK and pharmacy chains in Germany and Australia
- Onboarding of Blooms The Chemist, ranging HIV Self-Test as a core product
- 141 new pharmacies onboarded in Australia during FY2024
- Expanded market launch in new territories, such as Colombia, Switzerland and Eastern Europe (Eastern European variant registered in Q1 FY2025)



ATOMO HIV SELF TEST

Future Outlook

- HIV self-testing is expected to grow to US\$531m by 2026 at a CAGR of 30%. High growth rate driven by convenience and privacy offered by self-testing as well as growing adoption of self-test policy and procurement of self-tests by public health bodies [\[LINK\]](#)
- Advanced planning to support launch of Atomo HIV Self-Test in the New Zealand pharmacy market in Q3 FY2025
- Anticipating roll out commencing Q2 FY2025 of a National Vending Machine Program funded directly by Federal Government through the May Budget (delay to scale resulting from time to manufacture and install machines)
- Evaluating opportunity to develop a 4th Generation HIV Self-Test on Pascal for the professional rapid test market
- Lobbying for policy changes to allow HIV self-testing at home for PrEP users seeking reduced burden to test in clinic every 12 weeks



FREE HIV TEST KIT

Discreet, easy to use, and highly accurate HIV self-testing kits
Test regularly for HIV in the privacy of your own home
Results in just 15 minutes

[Order your HIV self-testing kit](#)



ATOMO ACTIVE SYPHILIS TEST

Development Fully Funded via a CRC-P Grant - \$2.44m

MARKET OPPORTUNITY

- Syphilis, has re-emerged as a significant global public health threat with an estimated 7m new cases in 2022, according to WHO [\[LINK\]](#)
- Existing Rapid tests cannot distinguish between current active and past treated infections and are unsuited to test people that have had Syphilis previously
- Serology tests required to detect active syphilis infection are laboratory tests, not available point of care and take days to return a confirmatory result

** Independent studies show;>90% reduction in blood delivery errors & 100% reduction in buffer delivery errors – Pascal compared to standard multi-component kit (plus a 40% reduction in time to carry out the test)*

USER/CUSTOMER PROFILE

- Atomo is seeking to launch first a Professional use test, followed by a Self-Test variant for use in both public health and pharmacy retail channels
- Market research underway for the US market for both CLIA waived professional and OTC/consumer self-test channels.
- As with HIV, Atomo intends to supply direct in ANZ and via distribution partners in other markets



STRATEGIC FOCUS FOR FY25 / 26

The focus of the business is to grow revenues over the next two years so that the company can accelerate the next phase of its journey to become a leader in the commercialisation of novel rapid tests and test technology

Continued growth of the HIV business, through:

- Support of recently established pharmacy / retail channels in key developed markets such as Europe and ANZ
- Expand sales into public health channels in Australia and commence supply into European public health channels
- Continue to register and launch in new territories in markets as well as looking to expand rapid test usage in channels such as PreP users and Professional use settings

Expanding the portfolio of Sexual health focused tests that Atomo offers through:

- Launching the AtomoNOW Active Syphilis test in ANZ and Europe and progressing the regulatory submission and commercial partner engagement in the US
- Continued focus on opportunities in Women's Health around blood pregnancy and iron deficiency
- Seeking to develop and commercialise opportunities related to home monitoring for applications such as Testosterone, Prostate health and of Vitamin D

Expanding the OEM supply business for Pascal and other new platforms through:

- Supporting partners rolling out Pascal enabled tests globally, including additional US approvals
- Securing supply agreements for new partners and products on the back of recent regulatory approvals driving entry into mainstream retail channels and leveraging increased market awareness

