



**ATOMO  
DIAGNOSTICS**

**FY25 RESULTS PRESENTATION  
29 AUGUST 2025**

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# CORPORATE SUMMARY

## WHO IS ATOMO?

- Headquartered in Australia, with a low-cost certified facility in South Africa, we develop, license, manufacture and supply innovative user-friendly rapid tests and test technologies to the global point-of-care test (POCT) market.
- Atomo's solutions are increasingly recognised for best-in-class ease-of-use and diagnostic accuracy, securing regulatory approvals for applications where reliability is critical.
- Proven performance in the hands of untrained users, with tests now commercialised, and offering significant potential as a leading solution in US CLIA-waived and self-test markets.
- Atomo's proven user focused development capabilities offer significant strategic value in a market increasingly driven by the need to deliver reliability and useability in decentralised settings

## WHAT DO WE DO?

- Atomo develops and supplies solutions that transform the user experience and minimise errors common in rapid blood test procedures:

Atomo Point of Care Finished Test products - an initial focus on sexual and female Health:

- HIV (commercialised)
- Active Syphilis (in development)
- Blood pregnancy (commercialised - partnership with NG Biotech)

Atomo Point of Care Test Technologies:

- Pascal (commercialised) – a fully integrated all-in-one cassette delivering an easy to do blood test, with performance validated in CLIA waived and Self-Test studies in the US and in Europe
- Florey (in development) – an integrated device that clips onto a standard cassette enabling existing in-market tests to upgrade seamlessly to Atomo usability



# CORPORATE ACTIVITIES DURING FY25

## BOARD RENEWAL

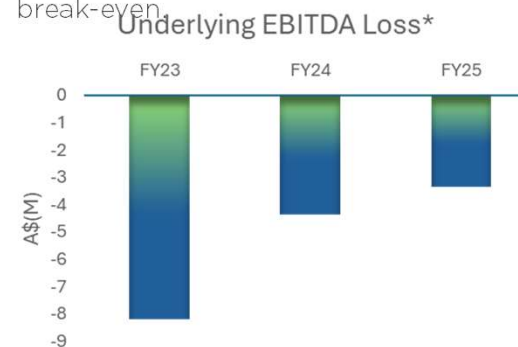
- Two new Non-executive directors with Diagnostic Industry backgrounds joins the Atomo board – Mr Anthony May and Mr Patrick Cook
- Three directors resign from the Atomo board – Mr John Keith (Chairman), Ms Debroah Neff and Dr Paul Kasian
- Dr Cheri Walker remains on the board and takes up role of Chair of Audit & Risk
- Managing Director John Kelly becomes Interim Chairman
- Overall annual board costs reduced from \$340k to \$140k

## CAPITAL ACTIVITIES TO SUPPORT BALANCE SHEET

- A total of \$2.96m raised in new capital (net of fees).
- The majority of new capital raised came from existing Atomo shareholders, with the remainder coming from new sophisticated and professional investors
- Shares issued at \$0.0185 per share with an attaching Option; exercise price of \$0.04
- Cash on hand as at 30 June of \$3.22m, with a further \$1.32m received in July/Aug in closing out capital activity

## CONTINUED FOCUS ON OPEX & BURNRATE

- Operating expenses have significantly moderated following Atomo's cost reduction strategies implemented since FY22, resulting in cumulative cost savings of over \$4 million over the past four years.
- Operating costs continued to moderate during FY25, with future efforts focused on expanding Atomo's portfolio and progressing towards break-even.



## RECENT COMMERCIAL DELIVERABLES

### ATOMO FINISHED TEST BUSINESS

#### HIV:

- Atomo secures order for \$440k for HIV Self-Tests from NAPWHA (National At-home Mailout Program)
- Atomo secures order for \$220k for HIV Self-Tests from Thorne Harbour (National Vending Machine Program)
- Atomo secures a further order for \$440k for HIV Self-Tests from NAPWHA (National At-home Mailout Program)

#### Active Syphilis:

- Atomo secures Australian Government Grant for \$2.44m to develop a first-to-market Pascal based test for detection of Active Syphilis
- Atomo and Burnet Institute sign Global Licensing Agreement for Commercialisation of Active Syphilis
- The Active Syphilis test preliminary performance data demonstrates market leading specificity, distinguishing between Active and Prior-treated infections at the point-of-care

### ATOMO OEM TECHNOLOGIES BUSINESS

#### Pascal:

- Atomo and Lumos restructure the Pascal FebriDx agreement, and Lumos pay a US\$180k IP License Fee for their field of application
- Atomo secures order for ~US\$410k from Lumos for supply of Pascal for FebriDx tests in the US market
- Atomo indicates anticipated Pascal revenues of up to US\$6.9m over the first three years of the agreement to PHASE, with significant ramp up forecast in the latter years of the contract

#### Florey Device:

- Lumos secures exclusive agreement with PHASE for FebriDx product sales up to US\$316m over the six-year contract
- Atomo develops Florey - device to clip-on to standard test cassettes and deliver Atomo usability and reliability for existing in-market tests
- Florey presented to market at ADLM in the US and is promoted on DCN Dx's booth as an innovative solution for usability





# **FY 2025 FINANCIALS**

## FY25 PROFIT & LOSS

AUD	FY25(\$m)	FY24(\$m)*	(%)
Revenue	3.79	4.09	(7%)
Cost of sales	(1.87)	(2.48)	
Gross Profit	1.92	1.61	19%
Gross Margin	51%	39%	
Other income	1.52	1.09	39%
Employee benefits expense	(3.26)	(4.04)	19%
Foreign exchanges gains/(losses)	(0.01)	0.03	(133%)
Research and development costs	(0.62)	(0.24)	(158%)
Professional fees expense	(0.95)	(0.63)	(51%)
Inventory obsolescence expense	(0.13)	(0.17)	24%
Other expenses	(1.84)	(2.03)	9%
Underlying EBITDA	(3.37)	(4.38)	23%

- Quality of margin improved significantly from 39% to 51% YoY (reflecting a transition away from Global Health HIV business), resulting in overall increase in gross margin by \$310k / +19% YoY
- With ongoing cost savings initiatives implemented across the business in prior periods, operating expenses has moderated, with overall operating expenses reducing ~\$650k / +9% YoY\*\*
- With improved sales margins combined with a material reduction in operating costs, overall EBITDA losses reduced to \$3.37m for the year, an improvement of 23% YoY and reflecting an ongoing trend towards breakeven



## FY25 BALANCE SHEET

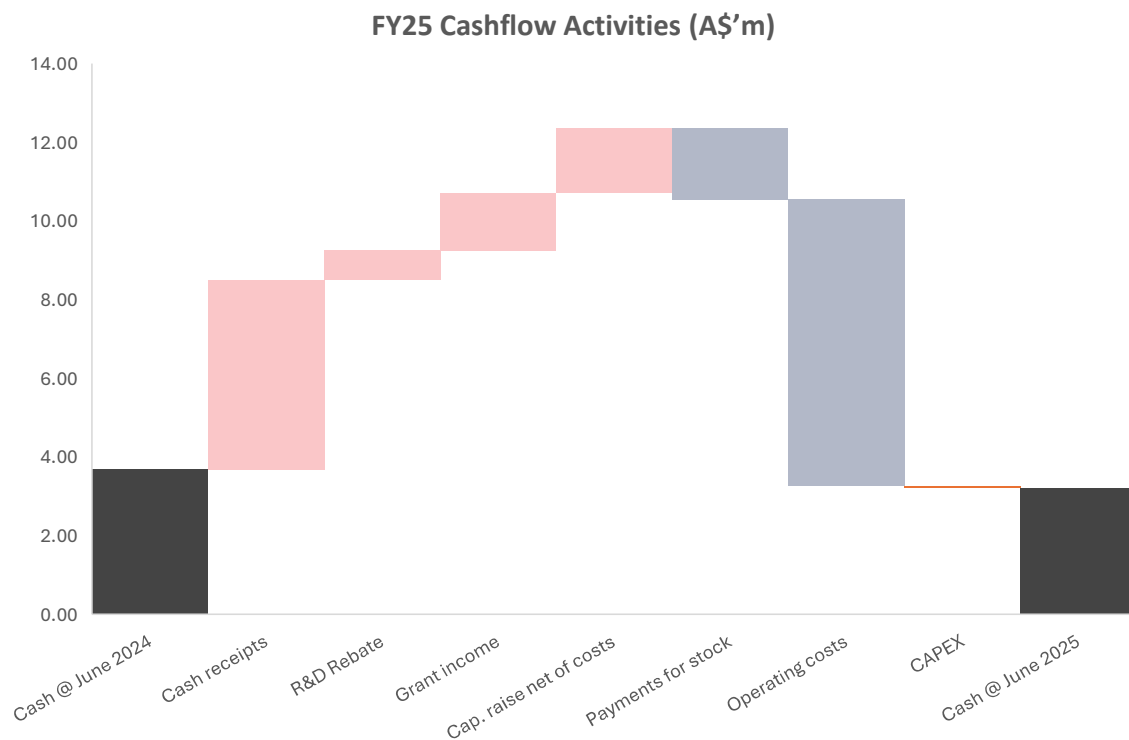
AUD	FY25 (\$m)	FY24 (\$m)
Cash and cash equivalents	3.22	3.69
Trade and other receivables	1.69	2.06
Inventories	1.65	1.84
Property, plant and equipment	0.89	1.64
Intangible assets	1.64	2.07
Other assets	0.18	0.08
<b>Total assets</b>	<b>9.27</b>	<b>11.38</b>
Trade and other payables	1.03	1.16
Other liabilities	1.28	0.13
<b>Total liabilities</b>	<b>2.31</b>	<b>1.29</b>
<b>Net Assets</b>	<b>6.97</b>	<b>10.09</b>

- Atomo had a cash balance of \$3.22m as of 30 June 2025, and the company remains debt free. Post YE, Atomo completed capital raise with ~\$1.32m net of transaction cost received in July/August 2025. Total capital raise of ~\$2.96m net of transaction costs
- Capitalised expenditure relating to R&D and PPE for the period was not significant
- Ongoing activities continues to focus on expanding HIV sales and increasing POC technology pipeline revenues (Pascal cassette supply and development of custom solutions).
- Increase in other liabilities relates to upfront grant funding received from CRC-P grant, accounting for ~\$1.07m of balance as at 30 June 2025





## FY25 CASHFLOW

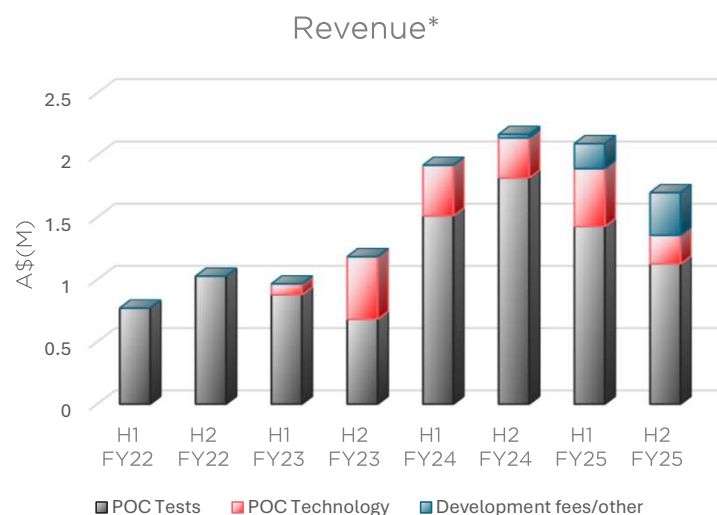


- Total Cash Receipts: \$8.7 million
  - ~\$4.8m from product sales
  - \$750k from R&D tax rebate
  - ~\$1.5m from CRC-P Grant for Active Syphilis test development
  - ~\$1.65m from capital raised (net of transaction costs)
- Total Cash Payments: \$9.1m
  - ~\$1.8 million in stock purchases
  - ~\$7.3m in operating expenses
  - Overall OpEx and CapEx remained in line expectations, supported by ongoing cost saving initiatives aimed at achieving breakeven
- The year-end cash balance of \$3.22m, no debt. Post YE, Atomo completed capital raise with ~\$1.32m net of transaction cost received in July/August 2025



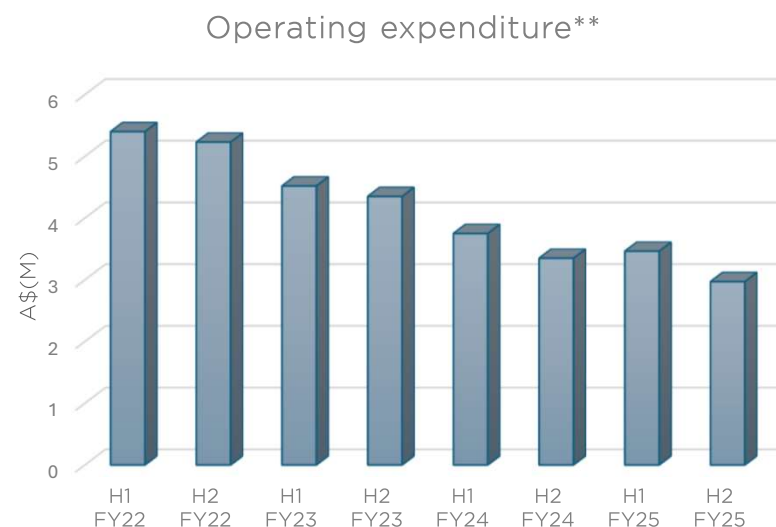
# FUNDAMENTAL TRENDS

Well positioned for profitability with no need for significant CapEx to fund future revenue growth and continued on-going trends to breakeven



Revenue, gross profit, and gross profit margin have all demonstrated material improvement compared to prior periods. This growth has been driven by:

- Expansion of point-of-care (POC) tests into high-income countries (HICs), and
- Diversification of revenue streams through Atomo's patented OEM technology and development capabilities.



Operating expenditure has moderated during the period, reflecting Atomo's continued focus over the past three financial years on reducing costs without compromising revenue growth opportunities





# **ATOMO HIV SELF-TEST**

A LEADING TEST IN KEY MARKETS

# ATOMO'S HIV SELF-TEST

## ATOMO IS SEEING TWO KEY DRIVERS OF LONG-TERM GROWTH:

- Expansion of channel interest across Pharmacy/Retail post COVID
- Emergence of Public Health Procurement for HIV Self-Testing
- Australian HIV revenues more than doubled from \$600k in FY24 to \$1.4m in FY25
- Australian Federal Government adopts HIV Self-Testing in national policy and commits to Self-Test product procurement for the first time and scales up programs for Free to User mail out and Vending Machine programs nationally.
- Atomo launches in New Zealand through Chemist Warehouse
- New South Wales State Health launches the 'MyTest' Vending Machine program in NSW across 30 machines state-wide for launch; with more than 200 vending machines now operational nationally and expanding in FY26
- Atomo's HIV Test launched in leading UK retailers, Tesco Supermarkets and Boots Pharmacies as well as in pharmacy chains in Germany and across Australia
- Atomo announces a 5-year agreement with Newfoundland Diagnostics for UK & Europe, worth more than AUD\$5.4m, ensuring continued supply into key European retail channels



NSW Health HIV Vending Machine

## COMMERCIALISATION STATUS:

- Market Leader in public & private channels in Australia
- Atomo HIV self test now registered in over 30 countries with more than 4 million tests supplied to market to date



# GLOBAL OPPORTUNITY FOR HIV RAPID TESTING

## North America

- Atomo Pascal supporting a future CLIA waiver process, with validated usability in FebriDx™ clinical studies already in place
- Atomo Pascal STI solutions positively viewed by US STI clinicians (US KOL engagement)

### Opportunity:

- Pascal functionality & useability offers opportunity for OTC home use approval
- A HIV Gen 4 Professional use test with CLIA waiver has significant market potential, including emerging PrEP testing demand as rapid test market share grows

## LMIC (Developing Markets)

- Atomo HIVST is registered in over 30 LMIC countries,
- Supplied through a partnership with Viatris Pharmaceutical
- Low cost WHO certified Atomo facility in South Africa support margins in these markets

Challenges – Recent US Government policy to rollback USAID is negatively impacting tender based demand

### Opportunity:

- Atomo and Viatris currently discussing joint commercialisation efforts in private pharmacy retail channels in these markets.
- A bundle with Active Syphilis test from Atomo's low-cost African facility provides a unique product offering with high demand in these markets for both tests

## UK & Europe

- Newfoundland secured as an exclusive distributor for UK. Have ordered 275,000 tests in first two years of launch activity
- Test supplied through Tesco supermarkets & Boots pharmacies and endorsed by the Terrance Higgins Trust.

### Opportunity:

- Atomo HIVST continues to establish as the leading UK retailer pharmacy test
- Leverage success in public health supply in Australia and enter NHS HIVST channel and other European public health channels
- Expand European pharmacy channels beyond Germany, Netherlands & Poland (Agreement with NFLD now non-exclusive outside UK enabling alternate channel partners)

## ANZ

Atomo's HIV Self-Test is sold in retail pharmacy (out of pocket customer demand); and is also supplied free to user through growing public funded national vending machine and mailout to home programs – now fully funded by the Federal Government

### Opportunity:

- Continued growth in HIV Self test (at the expense of professional use centralised lab services testing)
- Gen 4 test mandated for use with PrEP testing, Atomo sees an opportunity to expand its Sexual Health portfolio to address this growing market opportunity





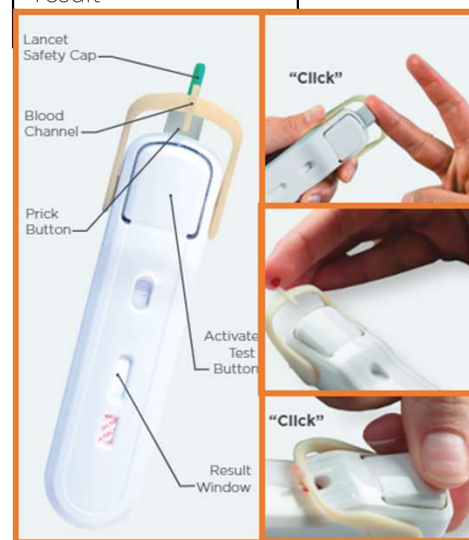
# **ATOMO ACTIVE SYPHILIS**

A UNIQUE TEST TO IDENTIFY ACTIVE  
INFECTION AT THE POINT-OF-CARE

## ATOMO'S ACTIVE SYPHILIS TEST

- As syphilis incidence rates increase, there is growing need for a rapid Syphilis test that accurately identifies active syphilis versus past treated syphilis
- Atomo's Active Syphilis Test exceeds the WHO Target Product Profile (we believe the first test to do so)
- Atomo's test can identify past treated samples as negative and with much higher accuracy compared to current tests that are reactive (positive) to prior treated patients with antibodies
- The Atomo Active Syphilis Rapid test may diagnose syphilis earlier than other commercially available antibody rapid tests (based on limited seroconversion panel testing)
- Developed on Pascal, the test has intuitive, user-friendly integrated blood collection, delivery and buffer reagent delivery, and with the test assay only requiring 10uL of blood, it ideally suited for use in CLIA waived settings and for Self-Test use

WHO TPP	Optimal	Atomo Test performance
Time to result	≤15 mins	15 mins
Specimen	Fingerprick max 20 µL	10 µL
Specimen preparation	Integrated	Fully Integrated Device
Steps between specimen preparation and result	One operator step, no timed interval	Intuitive, easy to use operational steps (greater than 99% concordance between untrained and professional users)



*Atomo Active Syphilis is still a treponemal test, but using specific TP antigens that measures IgA antibodies, significantly improving clinical specificity*



# LARGE EMERGING MARKET FOR SYPHILIS TESTING

- In 2022, WHO estimated approximately 8 million adults aged 15-40 acquired syphilis<sup>1</sup>
- The US reported syphilis case increased by 80% between 2018 and 2022<sup>2</sup>
- Australia has seen a threefold increase in syphilis cases in 10 years, with 6600 notification in 2023 alone. Alarming, 82% of these cases were among men who have sex with men (MSM) in urban areas, while in rural regions, 93% of cases were reported among indigenous populations<sup>3</sup>
- There is currently no rapid test available that can be accurately used to identify active syphilis infection
- The Syphilis testing market is estimated at US\$1.4bn by 2026, growing at a CAGR of 5.6%<sup>4</sup>





## ATOMO ACTIVE SYPHILIS – UNIQUE PERFORMANCE

Product	Type	Active Syphilis Detection	Blood Volume	Comparative Performance	
				Sensitivity	Specificity (patients with prior infection)
Bioline™ Syphilis 3.0	POC	No	20 µl	98.1% *	8.6% (patients, prior treated) 100% (never infected patients)
Determine™ Syphilis TP	POC	No	50 µl	100% *	0% (patients, prior treated) 94% (never infected patients)
Active Syphilis Test	POC and Self-Test	Yes	10 µl	100% β	83.3% ** (patients, prior treated) 99% (never infected patients)

\* Data presented on Bioline™ and Determine™ Syphilis TP are based on comparative lab performance at Burnet Diagnostics with SYSA samples, and additionally TP and RPR ≥1:16 for commercial samples with no clinical history for the Bioline 3.0 test. (This data was presented by Burnet Diagnostics at POC205 - Infectious Disease Conference, Thailand; June 2025).

\*\* Excluding patients with treated infections in the 3 months prior.

β All primary and secondary patients. Early latent patients with reactive RPRs.



# REAL CLINICAL BENEFITS DRIVES PATH TO MARKET

## BENEFITS OF ATOMO ACTIVE SYPHILIS

Compared to current generation syphilis antibody only rapid tests, Atomo's Active Syphilis test shows significant improvements in specificity resulting in:

- more efficient management of screening in developed markets
- ability to deliver accurate test and treat diagnosis at the point-of-care where extensive confirmatory testing is limited (developing markets)

Based on preliminary sero-conversion data, Atomo's test also appears to diagnose syphilis earlier in the infection cycle than existing antibody tests in the market

## KOL FEEDBACK

Recent engagement with key opinions leader clinicians (KOL) in the US and in Australia confirms strong support for the Atomo Syphilis test

- All respondents highlighted the value of differentiating between past-treated and active infection - something current rapid tests fail to do so
- Strong clinical value across key testing populations
- Test would be useful as at-home test, particularly in complaint PREP (HIV)

## INTENDED USE OF THE TEST

- The Atomo Syphilis Test is a single use rapid immunoassay for the qualitative detection of syphilis infection using a 10µl capillary blood sample. The test is intended for both professional and patients self-testing as an aid in the syphilis diagnosis in an easy-to-use lateral flow test format to provide a yes/no result in 15 minutes making it ideal for point-of-care use.
- The test is of particular use in being able to detect patients while infectious, regardless of their past treated status

## TIMELINE ON DEVELOPMENT

- Tech transfer and Set up of Manufacturing / Process Validation- Q2-Q3 FY 2026
- Engagement with TGA (Aus), BSI (EU) and US PreSub - Q2 FY 2026
- Commencement of Clinical trial for Australia and Europe - Q3 FY 2026
- Commercial path to market in Australia, Europe - early CY 2027





# **OEM TECHNOLOGY**

PASCAL AND FLOREY

# PASCAL CASSETTE

## CLINICALLY VALIDATED PERFORMANCE

### 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

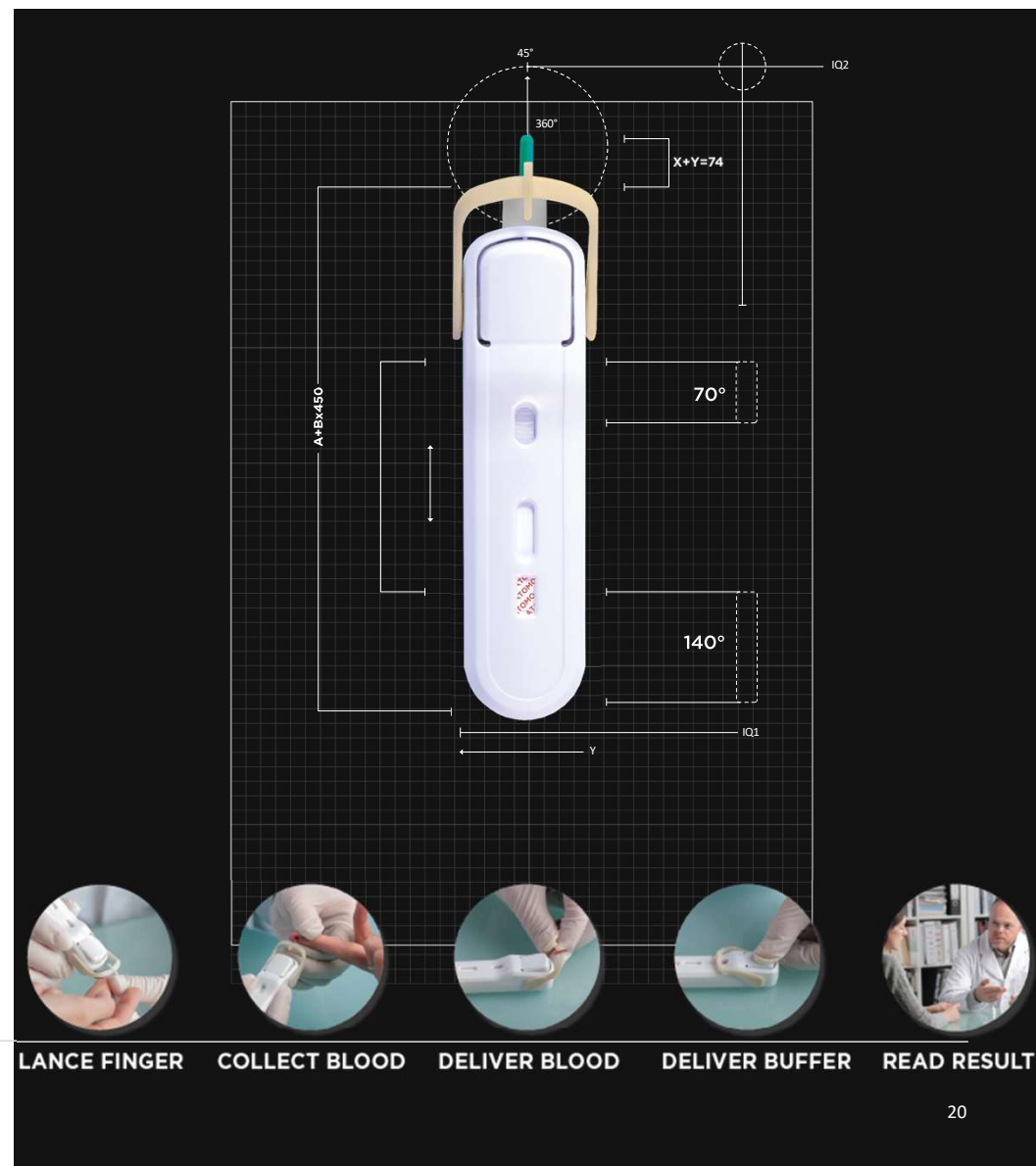
- Blood collection unit designed to collect and deliver the correct sample volume to the test strip

### Integrated Buffer Delivery

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

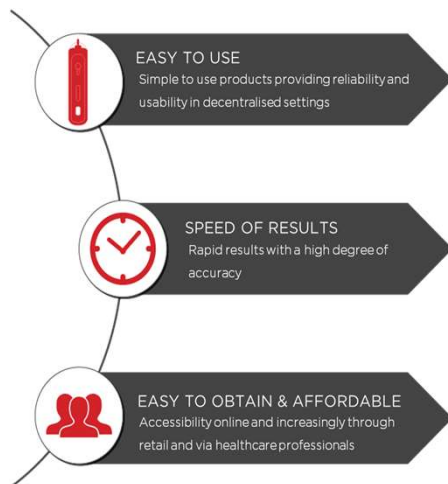
### Interlocked User Steps

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

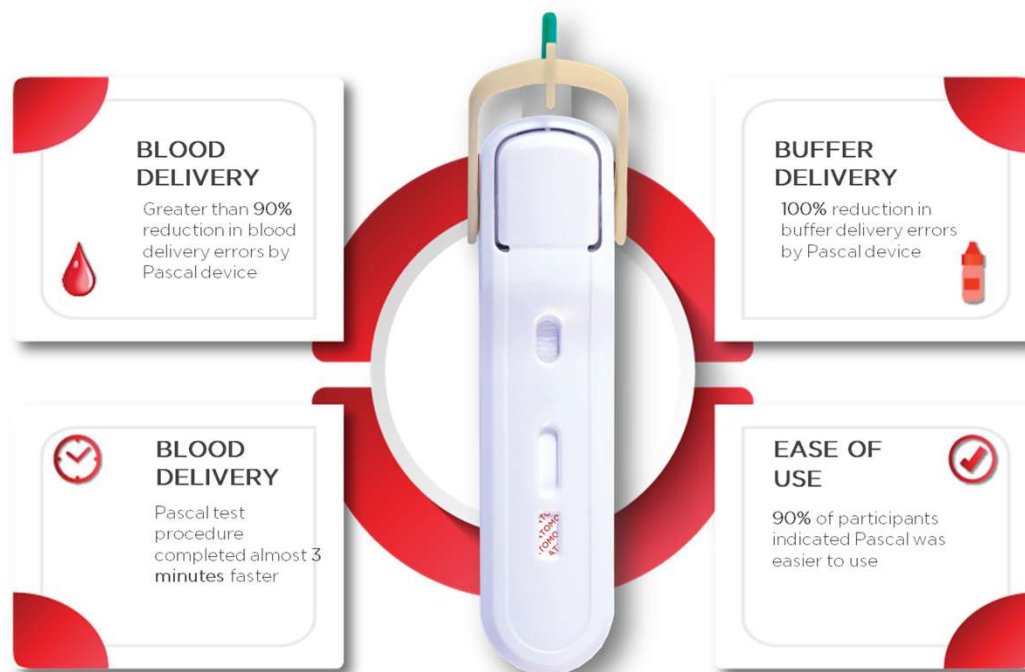


# SIMPLE TO USE, RELIABLE AND INCREASINGLY PREFERRED

## THE THREE KEY FACTORS DRIVING ADOPTION OF RAPID TESTS:



## EASE OF USE: WHERE ATOMO EXCELS:



## CLINICIAN & USER FEEDBACK

*"Simple to use! I've previously used the free HIV test but had difficulty' With this test I only needed a small amount of blood and got a result in minutes. Brilliant!"*

*"I would rather pay for this test in future if it means it is this easy - Thank you."*

*Atomo Self Test User ,UK,  
"Super easy quick test, top Feefo instructions and quickly implemented"*

*Atomo Self Test User ,  
Germany, Amazon*

*All surveyed users found it easy to use and said that they would recommend it to others.*

Future of Point of Care & Rapid Testing [\[Source\]](#)

Independent Report - Comparative usability analysis of Atomo Pascal vs Commercialised Blood Self-Test kit [\[Source\]](#)

*South Africa, Iyeza Health*



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## FLOREY CASSETTE (CLIP-IN)

Designed to minimise barriers to adoption with existing commercialised standard blood tests:

- Regulatory Burden - Florey is a usability accessory with lower barriers to introduction as the approved test assay cassette does not change
- Operations impact - existing manufacturing operations for the approved test strip, cassette and pouching remain unchanged

### Wide-Ranging Compatibility:

- Integrates with Standard lateral flow cassettes, including those validated for use with IVD desktop readers

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 blister allows for button activated delivery of the required reagent quantity to the test



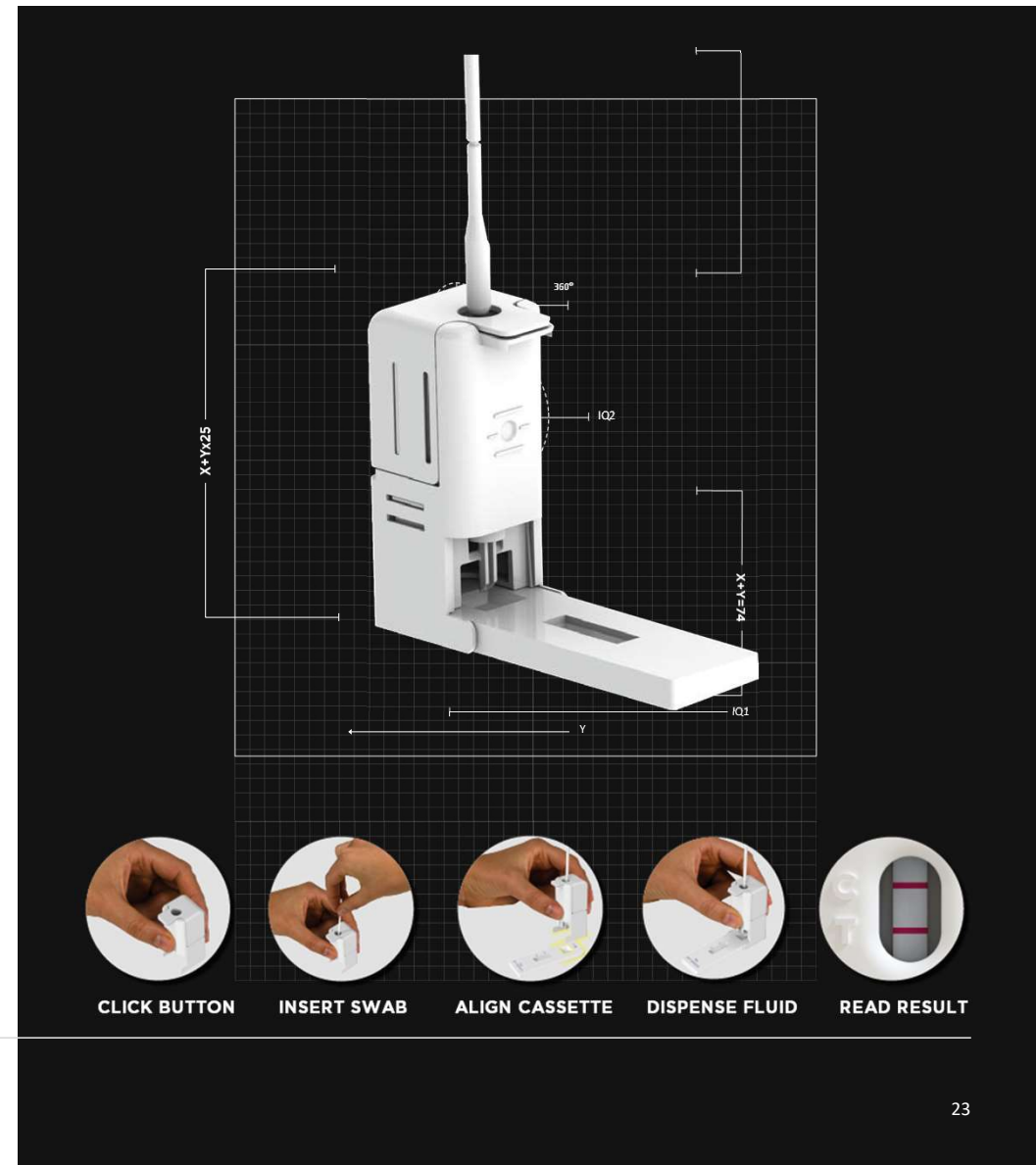
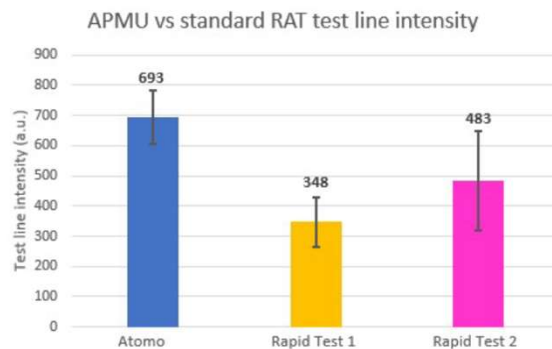
## CURIE CASSETTE (SWAB)

INTERNAL CHAMBER CAN BE RESIZED & OPTOMISED FOR NASAL, ORAL AND VAGINAL SWABS

Compatible With Existing Swab-Based LF Strip Tests, Curie simplifies workflow complexity, improves inter-operator variability and strengthens assay signal intensity

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

The Atomo Curie device delivers higher test line intensity than standard swab test formats





# **SUMMARY**



## INVESTMENT HIGHLIGHTS



- Disruptive innovator with unique user focused solutions
- Potential to disintermediate lateral flow point of care diagnostics.
- Strong revenue growth prospects across both finished products and OEM technologies businesses
- Access to multiple large, growing global diagnostic markets in Sexual Health testing and the Point-of-Care testing more broadly, with a supportive regulatory and clinical landscape post COVID supporting the adoption of decentralised testing
- Integrated user-friendly solutions for blood based decentralised testing (including CLIA waived and At-home settings)
- Multiple modalities established - enables multiple channels to market - pharmacy/retail, public health in clinic and at-home, and critical supplier of OEM technology products to other diagnostic manufacturers
- Leading user-centric design, device engineering, usability and regulatory capabilities now proven in several channels
- Successful approvals of integrated tests and devices with regulatory clearances in the US, UK, Europe, Australia, Brazil and across a number of other developing markets (S.E Asia, South America and Africa)
- Global market footprint - opportunity for entry into selected global markets/channels utilising and leveraging existing approvals, including the US, the UK & Europe, Australia, Brazil and a range of developing markets
- Commercially validated technology with more than 10 million units supplied to market and more than \$35m in aggregate sales
- Opportunity for significant margin growth at scale with CapEx already deployed and validated capacity in place
- Extensive IP Portfolio with more than forty registered patents (5 in the US)
- Numerous trade secrets and significant development expertise
- Exciting pipeline of finished tests and test technology in development



For more information, please contact:

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Atomo Diagnostics will deliver a presentation to investors at 11.00am (AEDT) (Tuesday, 2 September) via a live webinar.

To pre-register for this webinar, please use the following link:

<https://investors.atomodiagnostics.com/webinars/KyOJOr-atomo-diagnostics-end-of-year-results-fy25>

A copy of this investor presentation is available at the following link:

<https://investors.atomodiagnostics.com/link/PZ30Ey>

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

