



# ATOMO DIAGNOSTICS

(ASX:AT1)

# WHO IS ATOMO AND WHAT DOES IT DO?

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Atomo's portfolio of tests and technologies allows people to test early and test often, putting healthcare in the hands of the consumer

## WHO IS ATOMO?

- Headquartered in Australia and listed on the ASX, Atomo develops, manufactures and sells innovative rapid tests and unique test devices in point of care testing markets
- Atomo's solutions recognised as delivering best-in-class usability, accuracy and self-testing approvals
- A global company with commercial resources in the US, UK & Europe and an Atomo facility in South Africa
- Atomo's products offer a significant growth opportunity as the market continues to shift to decentralised and at-home testing post-pandemic

## WHAT DO WE DO?

Atomo's strategic focus is on two revenue generators:

- Point of Care Test Products  
HIV, pregnancy and iron deficiency tests for POC and at-home self-testing, distributed through an expanding global network, with more clinical applications to come
- Point of Care Test Platform Technology  
Unique blood and swab test devices and components, sold to partners with capability to incorporate other indications



# ATOMO'S BUSINESS: DE-RISKED, VALIDATED AND SCALING



## PRODUCT RISK

### STATUS

Designed to address user challenges with decentralised testing – now commercialised across a range of applications with registrations in more than 40 countries

### EXAMPLES/COMMENTS

Extensive positive customer experience  
Successful regulatory review and audit and approvals in multiple jurisdictions



## REVENUE / SALES RISK

### STATUS

Increasing HIV test sales, existing OEM customers purchasing devices, emerging consumer focus

### EXAMPLES/COMMENTS

Global health contract in place. Tesco and other retailers to stock Atomo manufactured HIV and other self-tests



## MARKET RISK

### STATUS

Key stakeholders now support home testing with strong tailwinds such as growing consumer interest, public health adoption & procurement and regulatory acceptance of testing at-home

### EXAMPLES/COMMENTS

TAM very significant, with >2bn rapid tests per annum globally with strong growth anticipated in the consumer segment



## REGULATORY RISK

### STATUS

Class IV (highest) approvals in place for Europe, Australia and WHO PQ (HIV Self-Test) with a number of clinical applications approved on Atomo cassettes for both professional and self-test, and US 510k obtained in July 2023

### EXAMPLES/COMMENTS

HIV Self Test  
COVID Antibody Test hCG  
Pregnancy Self Test FebrIDx  
AMR



## USER ACCEPTANCE

### STATUS

Performance independently established with common user errors reduced by 90% and overwhelmingly acknowledged by the vast majority of consumers as 'easier to use'

### EXAMPLES/COMMENTS

User error rates significantly reduced  
Consumers prefer the Atomo test



## DISRUPTION RISK

### STATUS

Extensive IP portfolio and proprietary know how protects first mover advantage, with industry leading usability and human factors expertise

### EXAMPLES/COMMENTS

Patent protection globally across 5 patent families covering all key healthcare markets



## TECHNOLOGY RISK

### STATUS

Volume supply across various applications, with functionality and reliability now established. Atomo's finished products combine Atomo devices with well accepted commercialised rapid test assay

### EXAMPLES/COMMENTS

**More than 5 million tests delivered**



# KEY ACHIEVEMENTS FOR FY23

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## Finished Test Products Business:

- Atomo entered into new HIV agreements to secure a \$1.9m take or pay deal for the South African private sector and an initial order for the UK retail market worth \$910k with a larger follow-on order contracted prior to 30 December 2023
- Atomo entered into a new agreement with NG Biotech to secure exclusive rights to commercialise the Pascal blood pregnancy test for key markets including Australia & NZ, the US and Canada; submission to TGA and pre-sub in process with US FDA

## Point of Care Test Platform Business:

- Re-emergence of non-COVID revenue streams post-pandemic: NG Biotech and Lumos both recommencing ordering of Pascal devices from Atomo; NG launching their product in France, the UK & Brazil and Lumos securing 510k clearance for their product in the US
- Entering into partner reseller agreements with three rapid test development companies (two in the US and one in Europe) to increase market access to and promotion of Pascal devices for new tests being developed and commercialised

## Corporate:

- Reduction of Operating Expenses of approximately \$1.5m over the FY23 period, with further savings being implemented for FY24
- Continued prudent cash management seeing the company close out the FY23 period with \$6.47m cash on hand, remaining debt free with a further \$2.25m in funding received after year-end through the completion of a Placement and SPP



# FY23 – PROFIT & LOSS

AUD	FY23(\$m)	FY22(\$m)	(%)
Revenue	2.54	12.34	(79%)
Cost of sales	(1.88)	(8.09)	
<b>Gross Profit</b>	<b>0.66</b>	<b>4.25</b>	<b>(84%)</b>
<b>Gross Margin</b>	<b>26%</b>	<b>34%</b>	
Less COVID RAT sales	0.39	10.42	
<b>Normalised Revenue</b>	<b>2.15</b>	<b>1.92</b>	<b>12%</b>
<b>Normalised Gross Margin</b>	<b>37%</b>	<b>27%</b>	
Other income	1.15	2.70	(57%)
Employee benefits expense	(4.85)	(4.10)	(18%)
Foreign exchanges gains/(losses)	0.11	0.09	(22%)
Research and development costs	(0.60)	(1.41)	57%
Professional fees expense	(0.82)	(2.33)	65%
Inventory obsolescence expense	(1.17)	(0.36)	(225%)
Other expenses	(2.54)	(2.50)	(2%)
<b>Underlying EBITDA</b>	<b>(8.06)</b>	<b>(3.66)</b>	<b>(120%)</b>

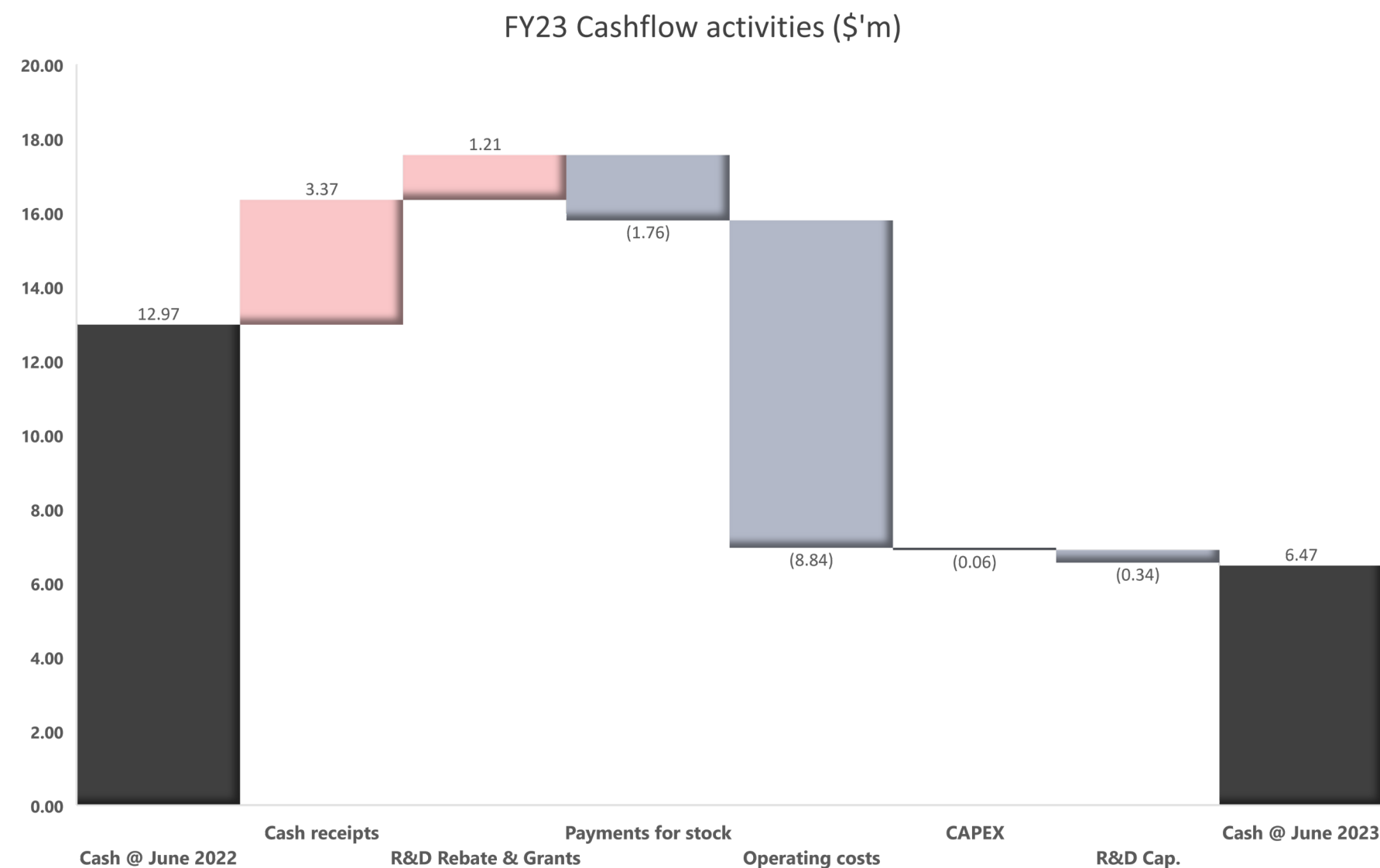
- Total customer revenue of \$2.54m is lower than the prior financial period as the COVID-19 pandemic passed, and with it, demand for COVID-19 rapid antigen and rapid antibody tests.
- After normalizing for COVID-19 sales, revenue increased by 12% when compared with FY22
- Non-COVID-19 revenue of \$2.15m includes sales from HIV POC Test of ~\$1.56m and POC technology of \$~590k
- Purchase orders received late in FY23 being delivered in Q1 FY24, including from Newfoundland Diagnostics, NG Biotech and Lumos Diagnostics
- After normalizing for COVID-19 sales, gross margin was 37%
- An inventory obsolescence expense relating to remaining COVID-19 rapid antigen stock negatively impacted EBITDA but did not have a cash impact during the period
- Ongoing measures were implemented during the year to reduce operating expenditure, reflected in an overall reduction of approximately \$1.5m, or \$130k per month (excluding the one-time inventory obsolescence expense). There is the potential for further additional cost savings during FY24





# FY23 – BALANCE SHEET AND CASH FLOW

AUD	FY23 (\$m)	FY22 (\$m)
Cash and cash equivalents	6.47	12.97
Trade and other receivables	1.82	2.68
Inventories	2.14	3.42
Property, plant and equipment	2.50	3.67
Intangible assets	3.30	3.57
Other assets	0.23	0.32
<b>Total assets</b>	<b>16.47</b>	<b>26.63</b>
Trade and other payables	1.43	1.08
Other liabilities	0.25	0.74
<b>Total liabilities</b>	<b>1.68</b>	<b>1.82</b>
<b>Net Assets</b>	<b>14.79</b>	<b>24.81</b>



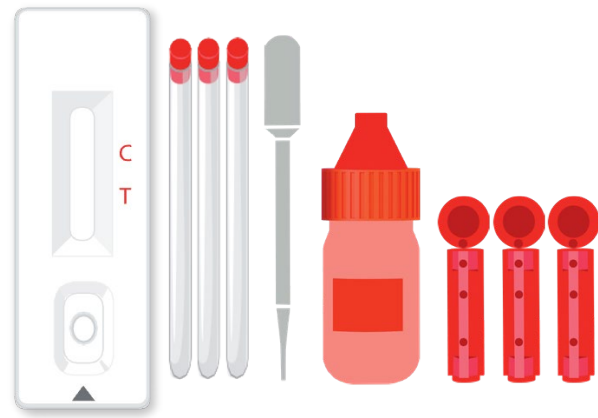
- Investment activity across the year primarily focussed on supporting market facing and revenue generating activities, including preparing for the launch of new novel tests in FY24 including tests for early pregnancy detection and monitoring iron deficiency

- Cash receipts of \$3.37m from customers
- Cash payments for stock of \$1.76m
- Opex, capex and R&D activities in line with expectations
- The year-end cash balance of \$6.47m does not include \$2.25m in post year-end funding



# ATOMO LEADS DISRUPTIVE INNOVATION IN RAPID TESTING

Atomo has developed best-in-class rapid tests that transform ease of use and reliability



***"I would rather pay for this test in future (than use a free test) if it means it is this easy"***

*"The lancet would not be out of place in a Christmas cracker"*

Home allergy test - Boots feedback page, UK

Atomo HIV Self Test user - Feefo, UK

## ISSUES WITH STANDARD RAPID TEST KITS

**COMPLEX:** Multiple components, too many steps, requires expertise

**HIGH ERROR RATES:** Difficult to secure regulatory approvals and customer acceptance

## ADVANTAGES OF ATOMO'S PRODUCTS

**SIMPLE & RELIABLE:** Intuitive to use, delivering accurate performance in the hands of untrained users

**UNIQUE:** The only fully integrated blood test for lateral flow applications



# DRIVERS OF THE ADOPTION OF RAPID TESTING

Adoption of decentralised testing driven by ease of use, speed and accessibility

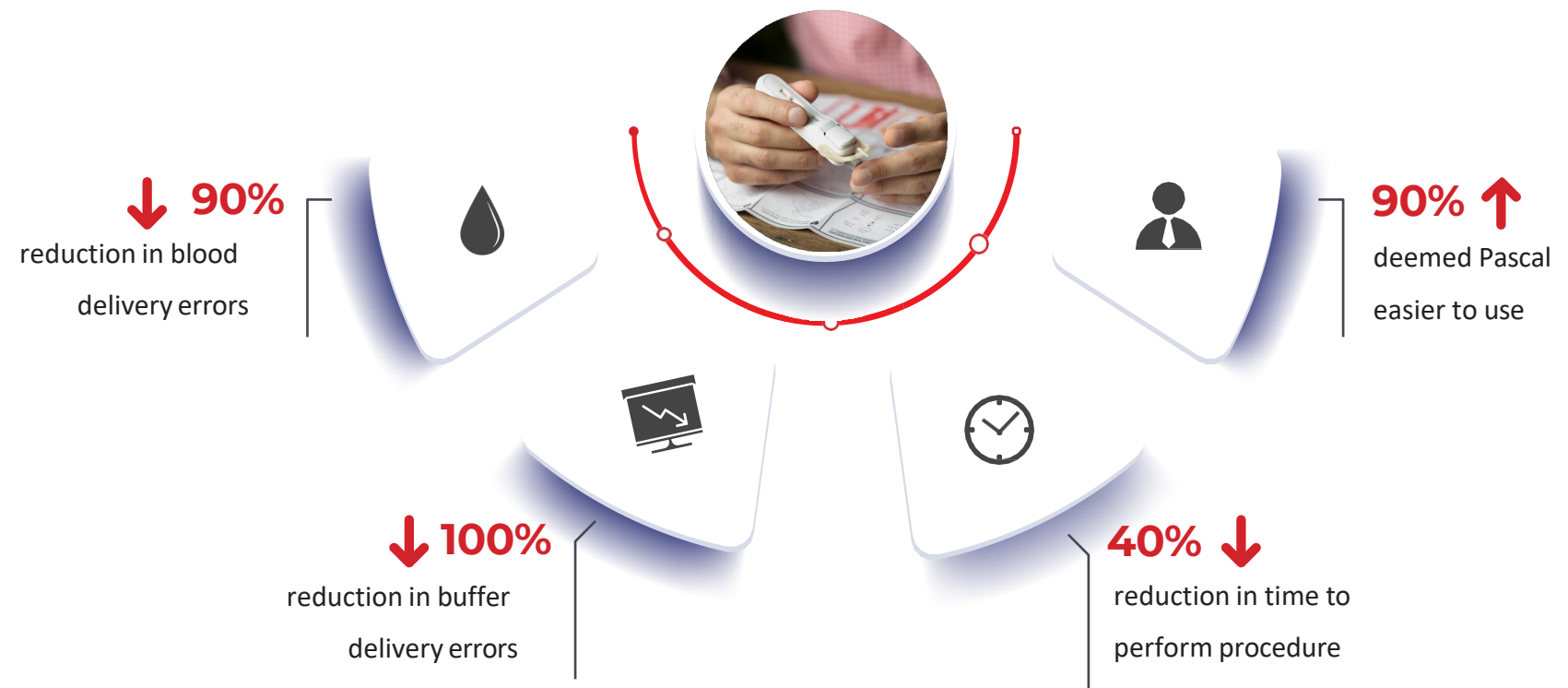
## WHAT DRIVES ADOPTION OF RAPID TESTING <sup>1</sup>



## ATOMO'S PASCAL DEVICE VS. COMPETITORS

An independent study was conducted to validate Atomo's Pascal device usability when compared to a standard multi-component CE marked self-test.

The study was conducted by an independent Australian CRO with 50 untrained participants performing a rapid blood test for the first time.



<sup>1</sup> [https://www.ipsos.com/sites/default/files/ct/news/documents/2022-03/ipsos\\_Future%20of%20POC%20and%20Rapid%20Testing\\_March%202022.pdf](https://www.ipsos.com/sites/default/files/ct/news/documents/2022-03/ipsos_Future%20of%20POC%20and%20Rapid%20Testing_March%202022.pdf)



# THE HOME TEST MARKET - RESPONDING TO CONSUMER DEMAND

New and incumbent industry players increasingly focused on at-home consumer test market

newfoundland



**amazon**

**Diagnostic Test Kit Range**

Our range of **self-diagnostics** is now available directly on **Amazon** in the **UK**.

Now Available

Consumer-Initiated Testing  
\$250M Revenues by 2025

## Abbott, BD, Quidel pursue DTC strategies amid 'paradigm shift' for at-home, self-testing

The three test makers said at last week's J.P. Morgan conference they see opportunities for direct-to-consumer, digitally-connected testing for diseases beyond COVID-19.

everlywell



## Test on Your Terms

At-home tests for wellness, nutrition, fertility, STDs and more. No copays, ever.

	<b>Food Sensitivity Comprehensive Test</b> ★★★★★		<b>Women's Health Test</b> ★★★★★
	<b>STD Test - Female</b> ★★★★★		<b>Metabolism Test</b> ★★★★★

\* The slide depicts general examples, not only specific Atomo Diagnostics products, customers or channels



# ATOMO'S HIV SELF TEST COMMERCIALISED AND SOLD GLOBALLY

Atomo has developed and successfully launched the world's first integrated, blood-based HIV Self Test which is now registered in 46 countries with over 1.5 million units sold\*



With regulatory approvals including CE Mark for Europe, Australian TGA and prequalification by the World Health Organization, the company's HIV business is poised to grow rapidly



Finished product assembly is carried out at the company's certified facility in South Africa, reducing the product cost of goods and logistics effort to supply volume into key global health markets, where Atomo's HIV Self test is registered in 39 LMIC countries



Contract signed with Newfoundland Diagnostics (worth \$2.1m in FY24) regulatory approval for Newfoundland HIV Self Test branded version obtained to support launch in Q1 FY24 in the UK and Europe, with product anticipated to be supplied by Newfoundland into leading supermarkets and pharmacy chains in the UK



HIV self-testing is increasingly being used by public health bodies around the world to scale up testing with Atomo having made significant progress in recent months with various levels of government in Australia



Atomo is now focused on further expansion of its HIV business and is seeking partners to support launch in markets where Viatrix is not yet registered, including in Central and South America, and Asia

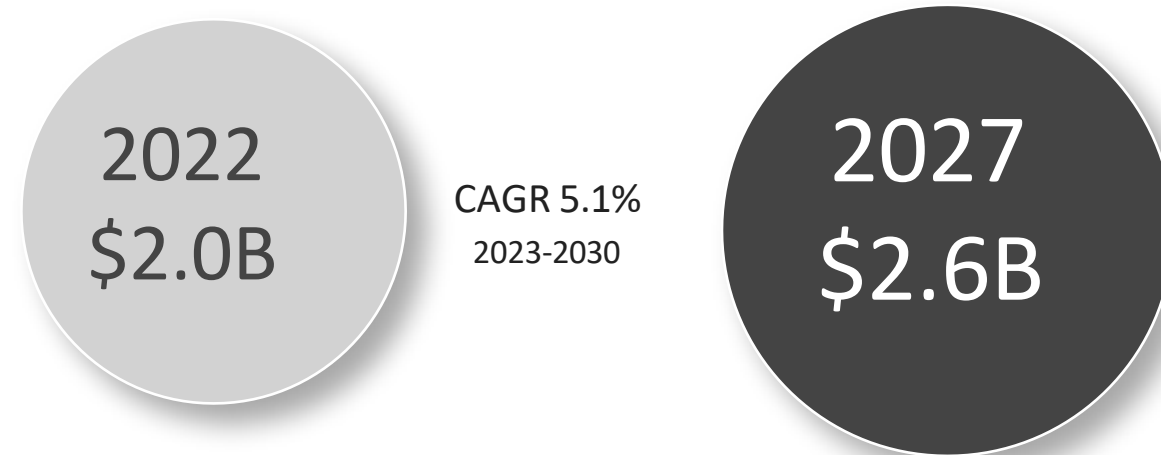
\* Excludes Professional Use tests sold



# PREGNANCY MARKET OPPORTUNITY

Atomo's early detection pregnancy test has a material opportunity to create a premium niche in the valuable female healthcare market

## GLOBAL PREGNANCY TESTING MARKET SIZE<sup>1</sup> (REVENUE AUD<sup>2</sup>)



- The US with around one-third of the global market share (2021) performs more than 30 million rapid pregnancy self-tests each year
- No early detection pregnancy blood self-test commercialised in developed healthcare markets. Clear opportunity for Atomo to take a first mover position in key markets
- The Australian pregnancy test market is estimated at more than 5 Million tests per annum
- Around half of the Australian women surveyed indicated they were either 'very or quite' interested in using the product, with one in five indicating a willingness to pay a material premium over the leading rapid urine tests<sup>3</sup>

## ATOMO'S OPPORTUNITY

The Atomo blood-based pregnancy test has significant benefits, advantages and differentiating factors:

- hCG levels build up earlier in blood than in urine, making blood a better sample type for early detection of pregnancy
- Extensive clinical studies show a high accuracy rate of 100% at hCG levels below 13 mIU/mL, making it an ultra-early pregnancy test. Early test detection urine tests typically claim performance at 25 mIU/mL
- Test anywhere, anytime. hCG levels in urine reduce significantly after morning first flow, while levels in blood stay constant, meaning a test can be bought and used straight away, any time of day
- Utilises the Pascal test device, offering a predicate for 510k pathway following recent 510k clearance of Lumos Diagnostics' FebriDx test on Pascal

**TGA are actively reviewing the product dossier submitted in April with regulatory approval and product launch in pharmacy anticipated over the next six months**

<sup>1</sup> Market Data Forecast Global Pregnancy Testing Market Size, Share, Trends, COVID-19 Impact and Growth Analysis Report, January 2022

<sup>2</sup> USDAUD 1.48

<sup>3</sup> Detailed survey conducted by Hummingbird Research, July 2023





# FUTURE PRODUCT ROADMAP

Atomo has a strong pipeline of product development moving beyond infectious diseases to target women's health and at-home wellness monitoring

2024

2025 AND BEYOND

## IRON DEFICIENCY / FERRITIN



Atomo is commercialising a blood-based rapid test to detect iron deficiency and then confirm the efficacy of subsequent treatment. To be manufactured in Atomo's certified HIV facility in Cape Town.

Atomo is targeting approval and launch in Australia and New Zealand within the next 12 months with the UK and Europe to follow later in 2024.

## VITAMIN D



Atomo is developing a simple to use test that enables users to identify if they are vitamin D deficient and then assess the effectiveness of treatment or lifestyle changes.

Atomo is targeting approval and launch in Australia and New Zealand towards the end of 2024, with the UK and Europe to follow in early 2025.

## OTHER APPLICATIONS

Atomo is seeking to expand its finished products portfolio to include a range of applications. Tests of interest include:

- Testosterone monitoring:
- Thyroid function monitoring (TSH):
- HIV / Syphilis:
- Chlamydia/Gonorrhoea combo (utilising the Atomo swab platform)
- Coeliac disease
- Allergy

# STRATEGY AND PRIORITIES FOR FY24 AND BEYOND

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## **ATOMO STRATEGY:**

- Continue to establish Atomo's products and partner supported products as offering unmatched usability and reliability in key markets, including ongoing focus outside of LMICs where better margins can be secured
- Becoming the preferred test solution for companies wishing to build upon the consumer-initiated market opportunity post-COVID
- Growing Atomo's POC Technology business through continued delivery of best-in-class test solutions and supporting regulatory approvals for partners increasingly mindful of the need to improve user experience and performance of rapid tests in decentralised settings
- Expanding Atomo's commercialised technology platforms to include sample types beyond blood and seamless electronic results interpretation and link-to-care

## **FY24 PRIORITIES:**

- Launch the pregnancy test in Australia and NZ and commence clinical trials in the US with a view to securing a US Commercial partner in advance of product approval to de-risk 'go to market' for Atomo shareholders
- Complete product validation for Atomo's iron deficiency (Ferritin) test and submit dossier for regulatory approval in Australia, Europe & UK
- Continue to support NG Biotech and Lumos as they continue to scale the commercial rollout of their Pascal based tests in global markets
- Secure new POC Technology customers through Atomo's expanding reseller network supported by continued success of existing finished products in winning consumer health channel contracts and key market regulatory approvals

*This presentation has been authorised for release on the ASX's Market Announcements Platform by the Board of AT1.*

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