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Australia

Authorized by John Kelly, Managing Director



## H1 FY23 Results Presentation

FEBRUARY 2023

# INTRODUCTION TO ATOMO

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**Atomo Diagnostics Limited (ASX: AT1) is an innovative medical device diagnostics company supplying unique, integrated rapid diagnostic test (RDT) devices and finished point-of-care rapid tests to global partners**



Atomo develops, manufactures and sells innovative rapid tests and test devices that address unmet user needs in point of care testing, via its international operational and commercial networks



Increasing opportunity globally supplying Atomo finished tests to healthcare distributors and Atomo assembled devices and components to diagnostic test partners (OEM).



Atomo solutions now increasingly recognised as delivering best-in-class usability, accuracy and at-home approvals, and increased scope to expand the range of applications being with Atomo's technology



*The diagnostics landscape has changed post-COVID, with a much greater focus on decentralised and at-home testing, resulting in a significant increase in the level of inbound interest in Atomo's solutions and a rebuilding of the partnership and product pipeline*

# ATOMO'S VALUE ADD AND INVESTMENT CASE

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- ✓ **Market Leading Integrated Rapid Diagnostic Test (RDT) Devices** – Atomo is establishing itself as a leader in the development of innovative integrated rapid test devices. The next stage of business growth presents an opportunity to create a global leader in the growing decentralized and home-based rapid test market post COVID
- ✓ **Innovative User Focused Development** – Atomo has RDT platforms for blood and swab testing, and has a demonstrated track record, award winning unique product solutions, robust patents and proprietary knowhow
- ✓ **World Class People** - Atomo's people are health innovation experts, reimagining consumer focused solutions and delivering best in class usability in the growing point of care testing market. Any collaboration would enhance innovation, bring new user focused solutions to bear and drive incremental value for any prospective partnership
- ✓ **Leading Products and Solutions** - ability to leverage Atomo's validated, approved unique user-friendly device solutions for OEM and finished test channels in the US
- ✓ **Cost and Regulatory Optimisation** - combine Atomo's low-cost installed manufacturing and existing regulatory approvals for at-home blood testing with a partner's portfolio and market access to optimise production and go to market strategy across both portfolios to drive increased market share and extract cost synergies



# H1 FY23 - PROFIT & LOSS

AUD	H1 FY23(\$m)	H1 FY22(\$m)	(%)
Revenue	1.36	5.34	(75%)
Cost of sales	(1.12)	(3.58)	
<b>Gross Profit</b>	<b>0.24</b>	<b>1.76</b>	<b>(86%)</b>
<b>Gross Margin</b>	<b>18%</b>	<b>33%</b>	
Less COVID-19 rapid test sales	(0.39)	(4.51)	
<b>Normalised Revenue*</b>	<b>0.97</b>	<b>0.83</b>	<b>17%</b>
<b>Normalised Gross Margin*</b>	<b>39%</b>	<b>23%</b>	
Other income	0.61	2.16	(72%)
Employee benefits expense	(2.41)	(2.11)	(14%)
Foreign exchanges gains/(losses)	0.09	0.05	(80%)
Research and development costs	(0.38)	(0.74)	49%
Professional fees expense	(0.42)	(1.30)	68%
Inventory obsolescence expense	(1.05)	(0.06)	(2,168%)
Other expenses	(1.35)	(1.24)	9%
<b>Underlying EBITDA</b>	<b>(4.67)</b>	<b>(1.48)</b>	<b>(216%)</b>

- Total customer revenue of \$1.36m is lower than the prior comparable period as COVID-19 business fell away
- When revenue is normalised for COVID-19 sales, there is an increase of 17% compared with H1 FY22
- Non-COVID-19 revenue of \$970k includes \$870k relating to HIV sales and \$100k relating to sales of Pascal devices sales (with further large orders for both HIV and Pascal received after 31 Dec)
- COVID-19 demand slowed and inventories approached expiry, COVID-19 tests were sold at reduced costs, negatively impacting overall gross margins
- After normalising for COVID-19 sales, gross margin was 39%
- As at 31 December, \$1.06m in inventory was provisioned, primarily relating to COVID-19 professional rapid antigen tests
- The inventory obsolescence expense negatively impacted EBITDA but did not have a cash impact during the period
- Expenses moderating, and are within target at <\$1m per month



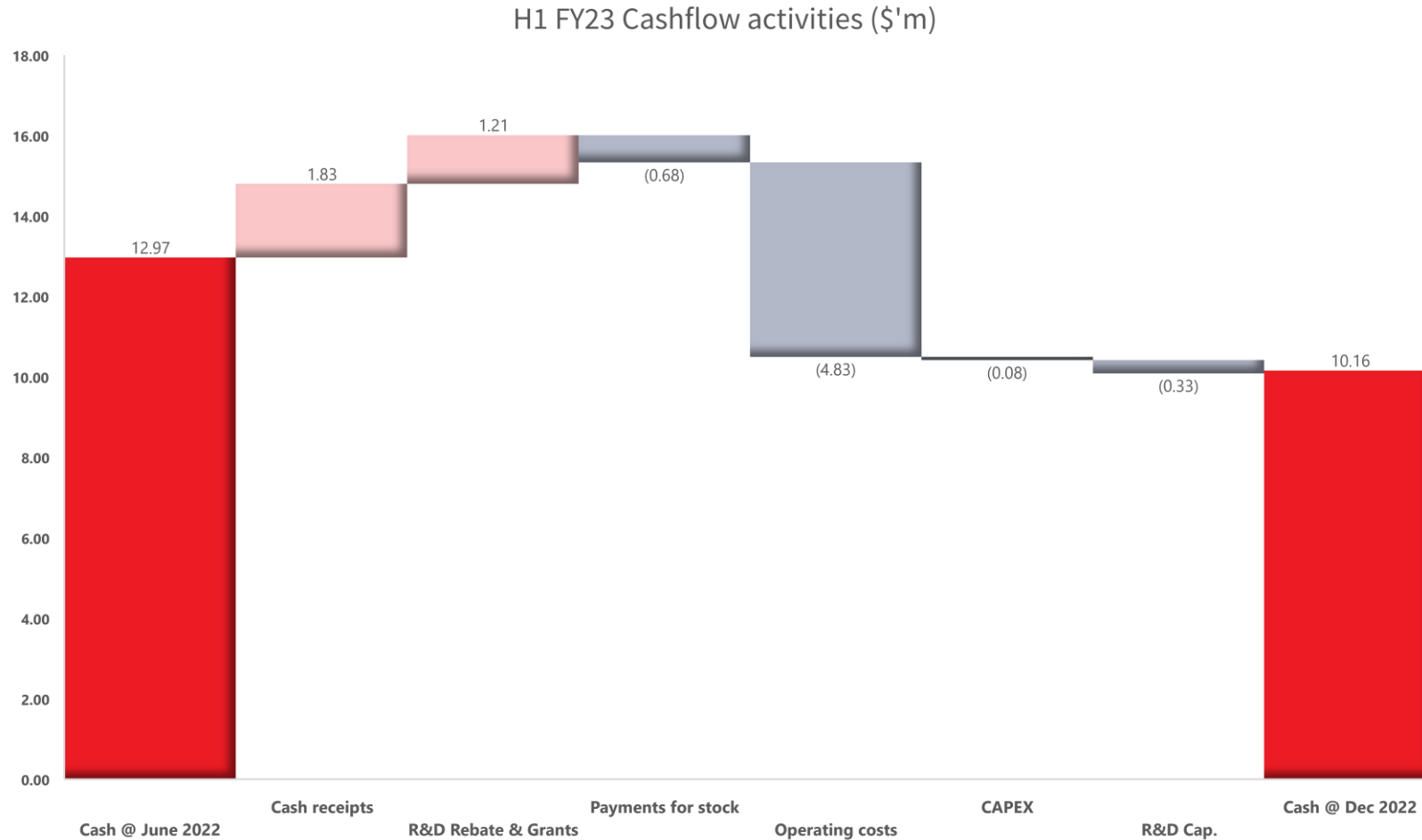
# H1 FY23 - BALANCE SHEET

AUD	H1 FY23 (\$m)	FY22 (\$m)
Cash and cash equivalents	10.16	12.97
Trade and other receivables	1.54	2.68
Inventories	1.93	3.42
Property, plant and equipment	3.04	3.67
Intangible assets	3.45	3.57
Other assets	0.25	0.32
<b>Total assets</b>	<b>20.37</b>	<b>26.63</b>
Trade and other payables	0.60	1.08
Other liabilities	0.61	0.74
<b>Total liabilities</b>	<b>1.21</b>	<b>1.82</b>
<b>Net Assets</b>	<b>19.16</b>	<b>24.81</b>

- Cash balance of \$10.16m at 31 December 22 and debt free
- Inventory balance reduced following the provision relating to COVID-19 professional use rapid antigen tests
- Capitalised expenditure relating to R&D and PPE was substantially reduced during the period when compared with FY22 as activities relating the blister machine and device development were largely completed
- Ongoing targeted investment continues to focus on expanding products utilising Atomo's existing technologies and IP



# H1 FY23 - CASH FLOW



- Cash receipts of \$1.83m from customers
- A further \$1.21m received from the R&D tax rebate and EMDG programmes
- Cash payments for stock of \$676k
- Opex, capex and R&D activities in line with expectations
- Total Cash outflow for the H1 period was less than \$2.8M



# DIAGNOSTICS LANDSCAPE AND TRENDS

## POINT OF CARE EXPERIENCING DISRUPTION & RAPID GROWTH

### Rapid testing – growth and increased acceptance

- Growing demand for reliable, rapid, decentralised diagnostic testing for patients at-home and supported by telehealth and reimbursement
- Point-of-Care testing has experienced accelerated growth during the pandemic and is the fastest growing segment of the diagnostics market
- Point-of-Care Diagnostics Market estimated to be worth USD50Bn by 2025\*
- Providers, payors, consumers, regulators and investors now understand and accept the unique role of point of care and at-home testing in the overall healthcare landscape\*

### Ease of use improves accuracy – this is critical to adoption

A recent survey of healthcare professionals\*\* confirms the top 3 key drivers for self-testing are:

- Speed of results – no lab turnaround time
- Ease of use – simple to use, accurate devices, easy sample collection at POC and at-home
- Easy to obtain – accessibility online, through retail and via healthcare professionals

### Point of care – driving investment

- Low-cost, easy to use point of care diagnostics with the ability to meet the demands of consumers and clinicians, are increasingly being seen as an attractive investment opportunity for industry players and investors seeking to back businesses disrupting traditional health care models

#### **Ease of Use**

For both home and POC, HCPs prefer devices that are easy to use, and interpret. They also want easy sample collection for both POC and home testing (saliva, cheek swab, urine and capillary small volume blood will be considered as the sample for the future).

*Ipsos, Future of POC and Rapid Testing, February 2022*

\* McKinsey & Co, *Telehealth: A quarter-trillion-dollar post-COVID-19 reality?* May 2021

\*\* Ipsos, *Future of POC and Rapid Testing*, February 2022

# STRATEGIC BUSINESS FOCUS

## CORE CAPABILITIES

Innovation, Device development, Usability, Regulatory Approval & Commercialisation

## BUSINESSES

### Point of Care Tests

- HIV & COVID-19 <sup>1</sup>
- hCG pregnancy <sup>2</sup>
- Ferritin <sup>3</sup>
- Vitamin D <sup>4</sup>

### POC Technology

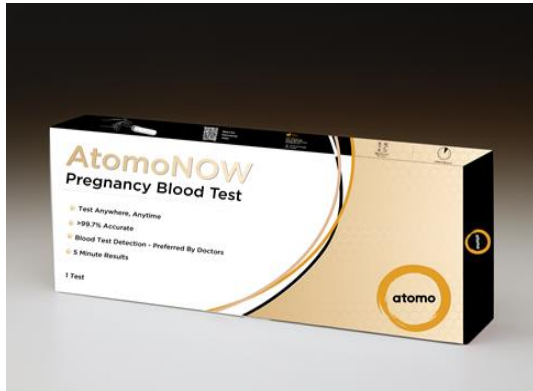
- Blood test devices
- Swab test devices
- Custom Reagent Blisters
- Licensed technology

## CHANNELS

- Rapid Test Distribution partners
- Co-commercialisation partners
- POC / Doctor office (Prof Use)
- OTC Retail /Telehealth/home health

## CHANNELS

- Sub assembly supply to OEM partners
- Bespoke design and development
- Co-commercialisation/licensing
- In-house supply for Atomo finished tests



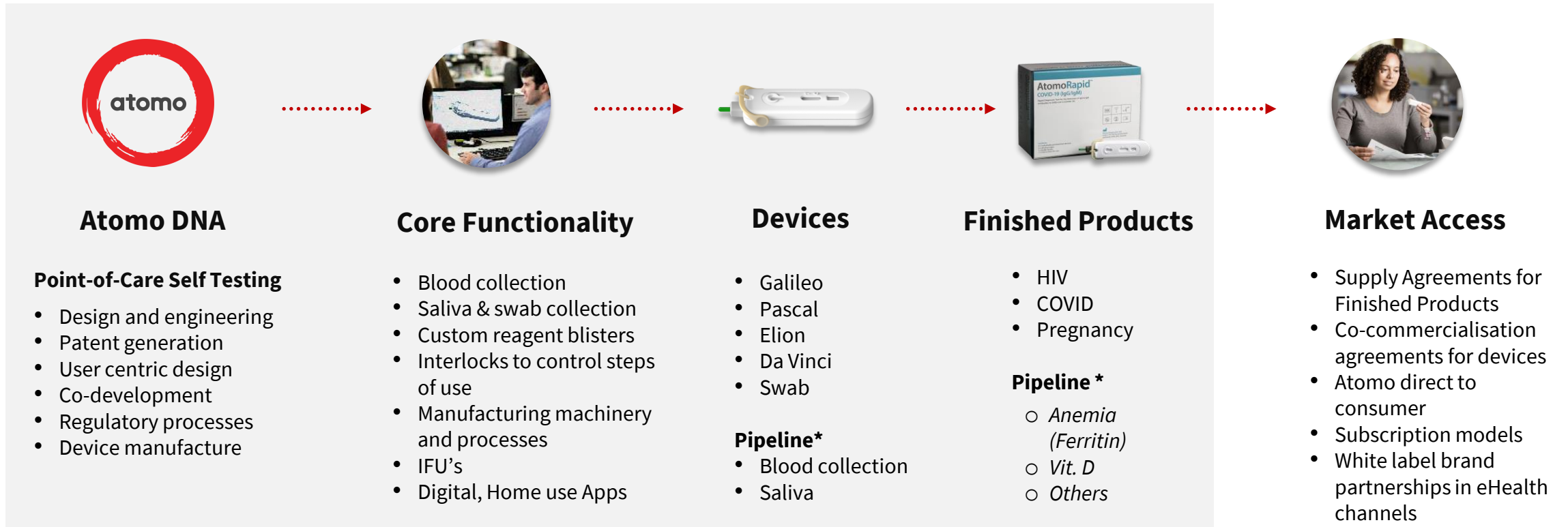


# UNIQUE CORE CAPABILITIES

IP Intensive



Less IP Intensive  
More customer focused



Atomo has commercialised rapid blood test devices with a level of integrated functionality and user simplicity unmatched in the rapid test market  
The company is now actively focused on commercialising integrated devices that materially improve testing with swab and saliva samples



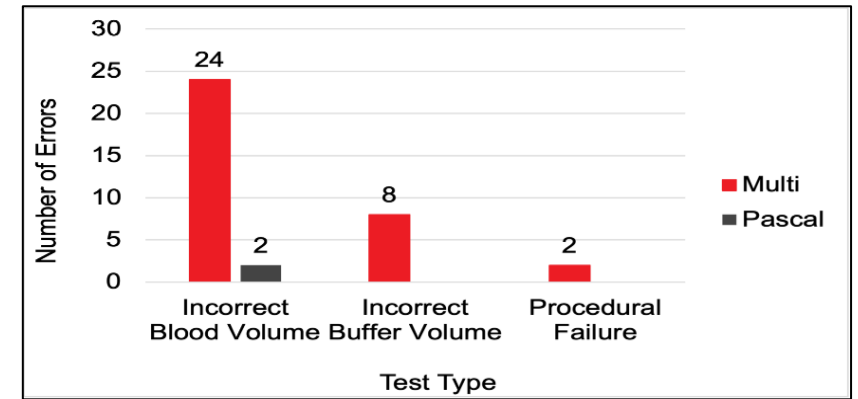
# BEST IN CLASS USABILITY

## UNMATCHED PERFORMANCE FOR BLOOD TESTING

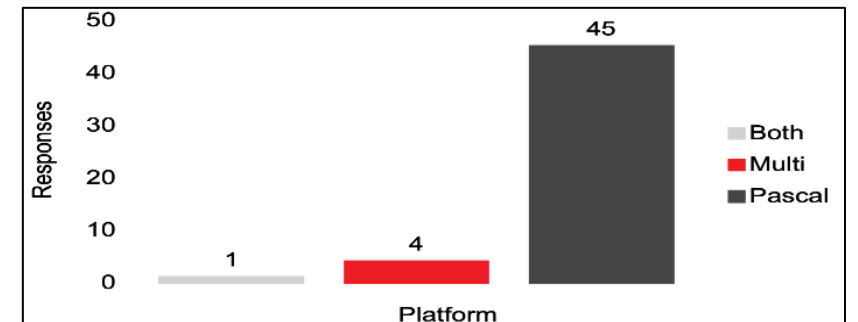
An independent usability study with users performing a rapid blood test for the first time using an Atomo Pascal test and a CE Marked Self-Test multi-component rapid test kit

### Outstanding Pascal Performance:

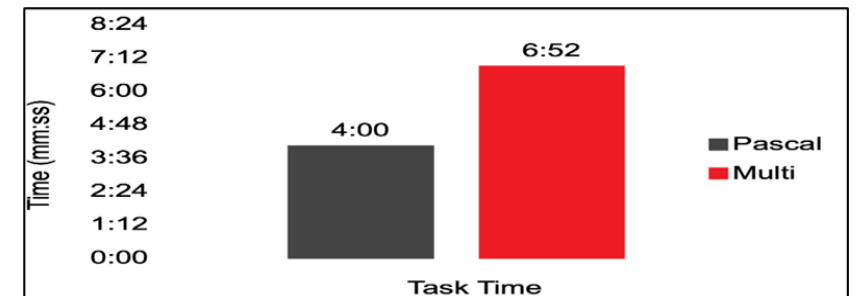
- 1. Greater than 90% reduction in incorrect blood volume errors** - Pascal reduced blood delivery errors from 48% down to 4% during first time use
- 2. 100% reduction in buffer delivery error** - an error rate of 16% seen with the test kit format completely eliminated using Pascal
- 3. Overwhelmingly easier to use** - 90% of participants said that the Pascal test was easier to use than the multi component test kit
- 4. 40% reduction in time to perform the Pascal test procedure** - participants using Pascal took 3 minutes less time to run their test procedure



*Significant reduction in critical errors - using Pascal compared to the multi component test kit product*



*Ease of use preference - 45 out of 50 users found the Pascal device easier*



*Quicker to run a test - Using Pascal saved around 3 minutes per patient*

# GLOBAL OPERATIONS & BUSINESS OPPORTUNITY

## NORTH AMERICA

- Rapidly growing at-home test channels post COVID
- Engaging with market on partnerships for Pregnancy and HIV
- Atomo US subsidiary established and a dedicated senior commercial resource based in U.S.A.
- US operations established



Atomo's proprietary blister manufacturing machine

## EUROPE

- Atomo HIV ST and HIV Professional use, blood-based pregnancy tests and FebriDx all CE marked
- Strategic partnership with NG Biotech for pregnancy testing
- Atomo UK subsidiary established and a dedicated senior commercial resource based in UK

## LMICs

- Atomo owned South African (SA) operations centre for HIV Manufacture, headcount: 20
- Viartis partnership covering more than 100 countries. Registration in 25 countries with 15 further national registration approvals pending
- HIV Self-Test production capacity currently ~3m p.a.

## ASIA

- Cassette moulding and assembly (current annual manufacturing capacity: ~20m)
- Seeking China market entry partner for Atomo products to address growing home testing channel

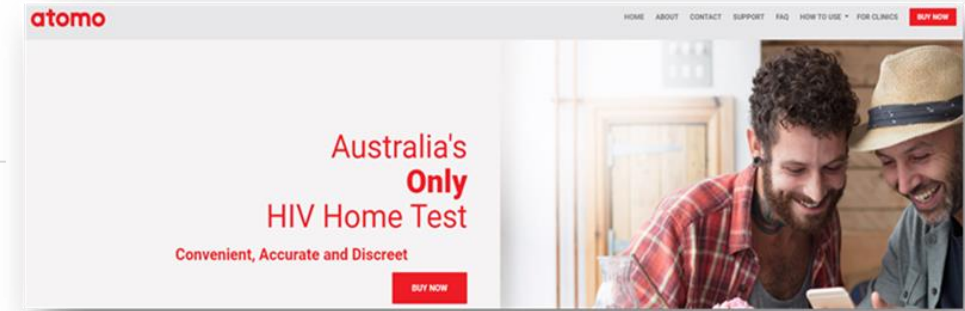
## AUSTRALIA

- Headquarters: Headcount 22
- Innovation Centre
- ASX listing
- ARTG listed products
- Direct to market capability with established brand recognition



# KEY PRIORITIES

## PRIORITIES FOR THE RAPID TEST BUSINESS



Growing the HIV business and delivering significant HIV sales growth over the next three years ;

- increased sales mix from developed markets where margins are materially better
- near term launch of a professional test through a new European distribution partnership
- expansion of sales in the Australian and European self-test markets (including in the emerging public health funded channel)
- completion of a commercial agreement for the US where we see significant opportunity

Securing regulatory approvals for an 'early detection' Atomo hCG pregnancy test in Australia & New Zealand and establishing go-to-market commercial partners in the US for professional use and at-home / retail channels

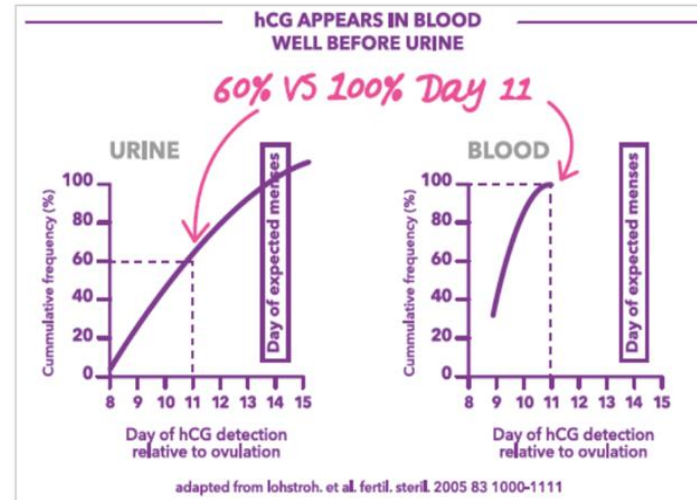
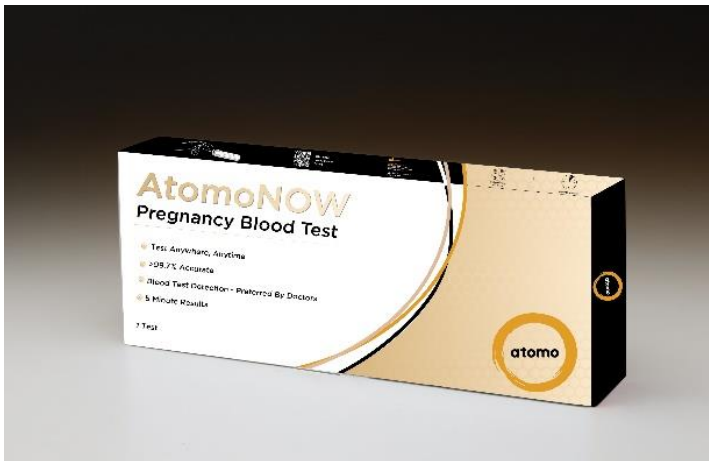
Securing regulatory approvals in ANZ & Europe for an Iron deficiency screening test (Ferritin), while assessing the commercial opportunity and costs to commercialise in that market

Continuing to build out a global distribution network to ensure market penetration and sales from Atomo's expanding list of finished tests



# EARLIER DETECTION OF PREGNANCY

- Intended use: Detection of early pregnancy in human whole blood samples
- AtomoRapid hCG is an immunochromatographic assay for the qualitative detection of hCG in human capillary whole blood collected from the fingertip with a sensitivity of 10IU/ml
- The test includes antibodies that specifically detect hCG and produces a coloured line in the “T” zone of the test if a positive result is obtained
- The reactive components are an anti- $\alpha$ -hCG monoclonal antibody and an anti- $\beta$ -hCG monoclonal antibody conjugated to a visual marker (colloidal gold)



x1 KIT

**Product advantages:**


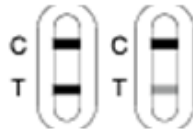
- An all-in-one device (lancet and integrated blood collector)
- A single drop of blood (10 $\mu$ L)
- Whole blood
- No sample transport
- Fast : result in 5 min
- Easy to interpret

# MONITORING FOR IRON SUFFICIENCY

## INTENDED USE:

The Ferritin rapid test is a rapid qualitative test in the Pascal Platform to determine if the level of ferritin in whole blood is above or below a certain cut-off (30ng/ml). The test would be suitable as a routine screening test that would be performed by a home test user (Self-test/OTC) and in POCT setting (reader based quantitation)\*.



RESULT	RECOMMENDATION
<b>Abnormal (Deficient: &lt;30ng/ml)</b> 	If just a control line appears and not test line, the result is abnormal. If the result is abnormal, it means that the ferritin level is lower than the normal (30ng/ml) and that you should consult the physician.
<b>Normal (Sufficient: &gt;30ng/ml)</b> 	Normal: Two lines appear. Both T (Test) and C (Control) line appear. This result means that the Ferritin concentration in blood is normal and that there is no potential iron deficiency.

## Target markets for initial launch in CY24:

Australia, New Zealand, Singapore & Europe



# KEY PRIORITIES

## PRIORITIES FOR THE POINT-OF-CARE TECHNOLOGY BUSINESS

Continuing to build out a customer base of rapid test manufacturers that choose Atomo's blood and swab test devices to commercialise their rapid tests

Securing 'reseller' commercial agreements in the US and Europe with lateral flow development companies that have access to new product development channels – this will provide direct market access for Atomo's blood and swab rapid test devices to new applications coming to market

Completing development of Atomo swab technology, including a version of the device optimised for emerging POCT segments such as rapid molecular and micro-fluidic based tests where integrate blister functionality is critical

Assessing partnership opportunities to support entry into the diagnostic blister reagent market where Atomo's proprietary integrated blister solution is considered by potential customers to have a number of advantages of existing products in the market

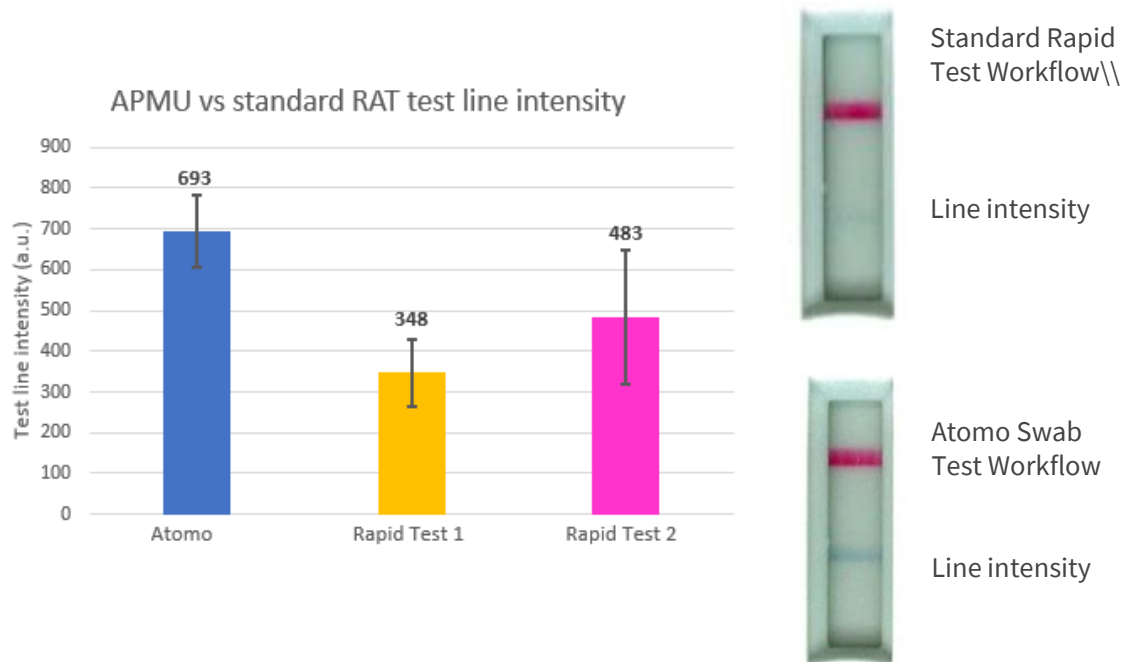


# ATOMO'S SWAB TEST SOLUTION

## TARGETING LATERAL FLOW, MOLECULAR AND MICRO-FLUIDIC MARKETS

### Key Takeaways

- In benchtop internal studies, the Atomo Swab Platform shows approximately 50% higher test line intensity than rapid test 1 and approximately 30% higher line intensity than rapid test 2.
- Testing was limited and did not use live diagnostic sample. Further diagnostic testing is required using defined control materials



### Key Takeaways

There are several functionalities delivering the improved performance of the Atomo Device compared to the standard kit:

- The volume of extraction buffer in each device is the required amount and no more: increasing concentration ratio of the sample
- The workflow of extracting the sample from the swab: extraction ribs vs squeezing plastic tube are more effective
- The volume of sample and buffer delivered to the test: substantially all of the sample is delivered



### Target applications for the swab device:

Home STI screening – Chlamydia & Gonorrhoea

Respiratory Panel testing – COVID/Flu/Strep



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