



ASX Announcement

2 November 2023

2023 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 2023 Annual General Meeting.

For more information, please contact:

John Kelly

Atomo Diagnostics

john.kelly@atomodiagnostics.com

Phone: +61 401 922 279

This announcement was authorised by the Managing Director & CEO.



ATOMO
DIAGNOSTICS

DISCLAIMER

This presentation has been prepared by Atomo Diagnostics Limited (“Atomo”) based on information available as at the date of this presentation. The information in this presentation is provided in summary form and does not contain all information necessary to make an investment decision. Reliance should not be placed on the information or opinions contained in this presentation. An investor must not act on the basis of any matter contained in this presentation but should make its own assessment of Atomo as part of its own investigations.

This presentation has been provided for general information purposes only. It does not constitute an offer, invitation, solicitation or recommendation with respect to the purchase or sale of any security in Atomo, nor does it constitute financial product advice or take into account any individual’s investment objectives, taxation situation, financial situation or needs.

Although reasonable care has been taken to ensure that the facts stated in this presentation are accurate and that the opinions expressed are fair and reasonable, no representation or warranty, express or implied, is made as to the fairness, accuracy, completeness or correctness of the information, opinions and conclusions contained in this presentation. To the maximum extent permitted by law, neither Atomo, nor any of its officers, directors, employees and agents, nor any other person, accepts any responsibility or liability for the content of this presentation including, without limitation, any liability arising from fault or negligence, for any loss arising from the use of or reliance on any of the information contained in this presentation or otherwise arising in connection with it. This disclaimer also extends to all and any information and opinions contained in, and any omissions from, any other written or oral communications transmitted or otherwise made available to the recipient in connection with the opportunity outlined in this presentation and no representation or warranty is made in respect of such information.

The information presented in this presentation is subject to change without notice and Atomo does not have any responsibility or obligation to inform you of any matter arising or coming to their notice, after the date of this presentation, which may affect any matter referred to in this presentation. The cover image is illustrative only.

This presentation may contains certain forward looking statements that are based on Atomo’s beliefs, assumptions and expectations and on information currently available to Atomo management. Such forward looking statements involve known and unknown risks, uncertainties, and other factors which may cause the actual results or performance of Atomo to be materially different from the results or performance expressed or implied by such forward looking statements. Such forward looking statements are based on numerous assumptions regarding present and future business strategies and the business, economic and competitive environment in which they operate in the future, which are subject to change without notice. Past performance is not necessarily a guide to future performance and no representation or warranty is made as to the likelihood of achievement or reasonableness of any forward looking statements or other forecast. To the full extent permitted by law, Atomo and its directors, officers, employees, advisers, agents and intermediaries disclaim any obligation or undertaking to release any updates or revisions to information to reflect any change in any of the information contained in this presentation (including, but not limited to, any assumptions or expectations set out in the presentation).



WHO IS ATOMO AND WHAT WE DO?

Our unique portfolio of integrated 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, we develop, manufacture and supply innovative rapid tests and unique test solutions into point of care and self-test consumer markets
- Our solutions recognised as delivering best-in-class usability & accuracy and facilitating OTC/consumer approval for blood-based commercial applications
- Proven usability and existing blood-based self-test approvals in key markets gives Atomo potential to achieve and defend first mover success in the US OTC market
- Expanding globally with products registered in more than thirty countries and dedicated commercial resources covering the US, UK & Europe and S.E.Asia
- Atomo's products offer a significant growth opportunity as the market continues to shift to decentralised and expanded interest in at-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 for HIV, blood pregnancy and iron deficiency - POC and self-test
 - Clinical applications in pipeline across wellness and sexual health
- **Point of Care Test Platform Technology:**
 - Cassette solutions supplied to partners requiring improved usability and user preference, or seeking self-test / OTC channel access
 - Custom cassette solutions (blood and swab based) for partners seeking improved usability for POC reader solutions



ACHIEVEMENTS IN FY24

Atomo entered into a number of new HIV distribution agreements to focus on emerging opportunities in consumer retail channels post COVID-19, and access markets where products are not yet registered.

First 510(k) approval secured for a Pascal rapid test in the valuable US market, supporting Atomo tests and other OEM customers to bring further tests to market

Resumption and expansion of OEM business from existing customers following a hiatus in blood-testing during the COVID pandemic

Growth of our HIV Self-Test business in Australia through the rollout of the product in pharmacy channels, as we expand the pharmacy network, and increase engagement with government.

Renegotiation of our strategic relationship with NG Biotech to give Atomo exclusive commercial rights for the NG Biotech blood pregnancy test on the Atomo Pascal device for the US, Canada, Australia and New Zealand. Subsequent submission engagement with TGA in Australia and FDA in the US.

Securing a number of reseller commercialisation agreements with companies in the US and Europe that develop new rapid test assays for the market

Reduction in Operating expenditure of the business with cost reduction across the year of approximately \$1.5m



Atomo HIV Self-Test, CE Marked under the Newfoundland brand and launched in Tesco Supermarkets across the UK



AtomoNOW pregnancy test submitted for approval to TGA in April 2023

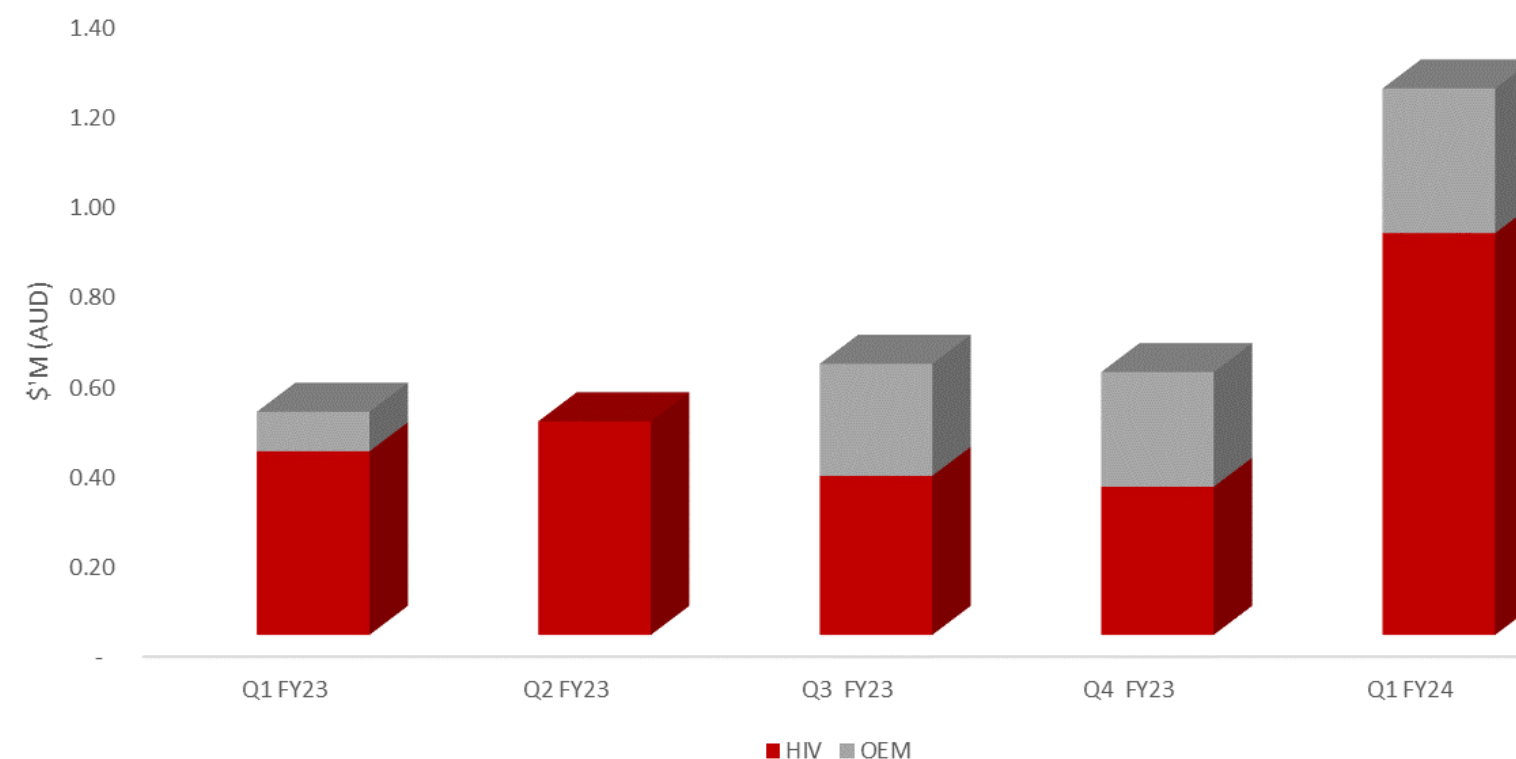


FINANCIAL PERFORMANCE FY24

AUD	FY23(\$m)	FY22(\$m)	(%)
Revenue	2.54	12.34	(79%)
Cost of sales	(1.88)	(8.09)	
Gross Profit	0.66	4.25	(84%)
Gross Margin	26%	34%	
Less COVID RAT sales	0.39	10.42	
Normalised Revenue	2.15	1.92	12%
Normalised Gross Margin	37%	27%	
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%)
Underlying EBITDA	(8.06)	(3.66)	(120%)

- After normalising for COVID-19 sales, revenue grew by 12% and gross margins improved to 37%
- Opex continues to reduce through FY23 and into FY24

Quarterly Revenue (excl COVID-19)

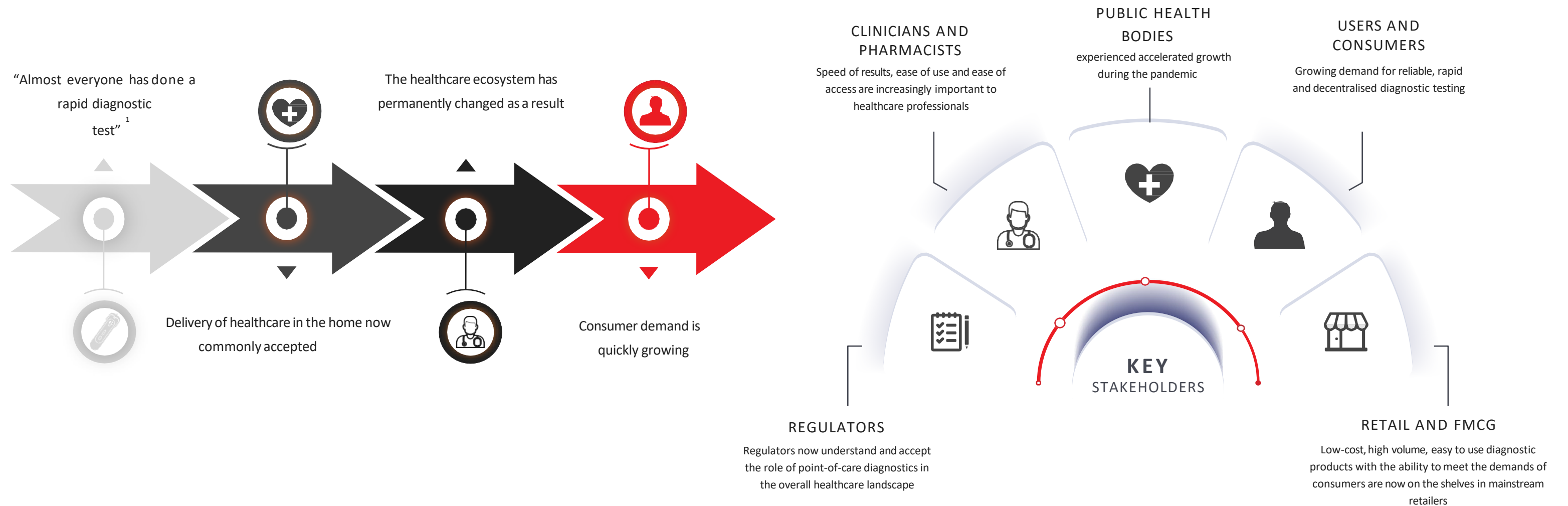


- Return to Quarterly revenue growth post-COVID as customers refocus, with Q1 FY24 reflecting improved non-COVID-19 sales in HIV and OEM
- Cash on hand at end of Q1 FY24: \$6.9 million



AN IMPROVED DIAGNOSTIC TEST LANDSCAPE

The landscape for diagnostic testing continues to transition away from hospitals and clinics post COVID-19. Key stakeholders in the healthcare eco-system, some previously resistant to decentralised rapid testing, lower costs, are increasingly acknowledging the convenience and proven efficacy of at-home diagnosis and treatment



¹ McKinsey & Co. Telehealth: A quarter-trillion-dollar post COVID-19 reality May, 2022



ATOMO LEADS USABILITY INNOVATION IN RAPID TESTING



Standard multi component test kit

Pascal 'all in one' test



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

Home allergy test - Boots feedback page, UK

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

Atomo HIV Self Test user - Feefo, UK

COMPLEX: Multiple components, too many steps, requires expertise

SIMPLE & RELIABLE: Intuitive to use, delivering accurate performance for untrained users

HIGH ERROR RATES: Difficult to secure regulatory approvals,

UNIQUE: The only commercialized fully integrated blood test solution

Surveyed US clinicians believe three things are necessary to drive continued rapid test adoption:

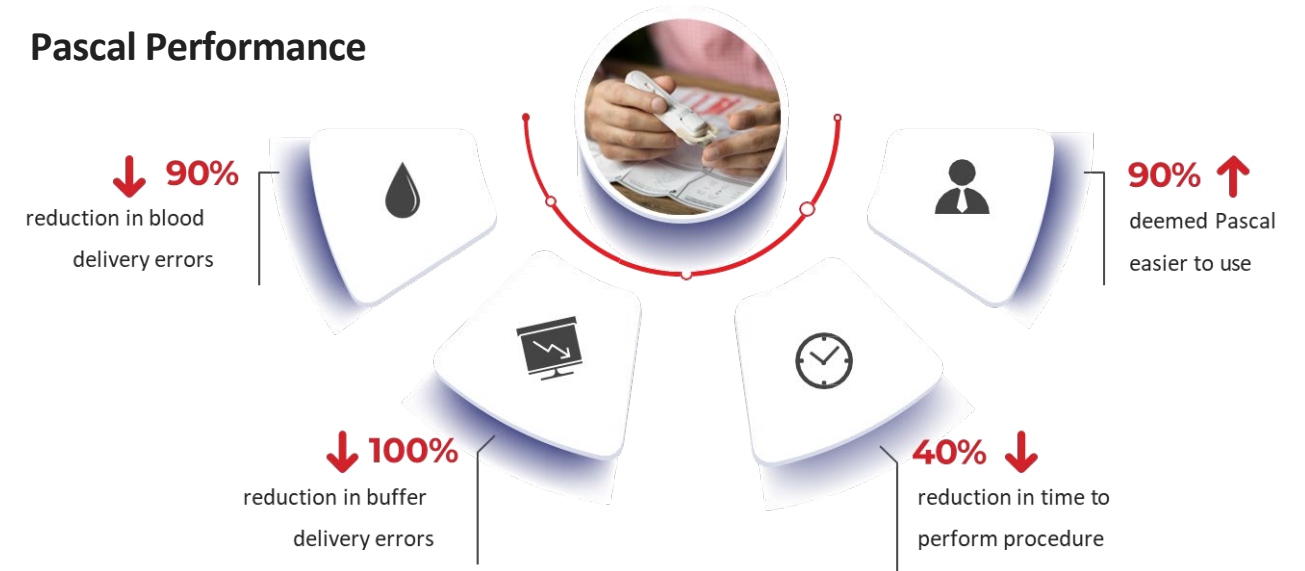
Standard test kit formats deliver quick results and affordability, but only Atomo's Pascal solution delivers inherent ease of use and simplicity for blood applications

Recent 510k approval by FDA for a US manufactured test on Pascal provides predicate for future products – CLIA waiver pending. OTC to follow.

WHAT DRIVES ADOPTION OF RAPID TESTING ¹



Pascal Performance



¹ https://www.ipsos.com/sites/default/files/ct/news/documents/2022-03/ipsos_Future%20of%20POC%20and%20Rapid%20Testing_March%202022.pdf



ATOMO'S HIV SELF TEST INCREASINGLY SUPPLIED GLOBALLY

Atomo saw momentum in its HIV business over the last year developed. The Atomo HIV Self-Test is now registered in more than 40 countries with nearly three million HIV Tests sold globally



With Tier 1 regulatory approvals including CE Mark for Europe, Australian TGA and prequalification by the World Health Organization, the company's HIV business is growing rapidly post COVID



Atomo's latest HIV contract is with UK based Newfoundland Diagnostics. Initial order for 200k self-tests supporting recent launch across Tesco supermarket stores in October, with a further 210k tests to be ordered by end of 2023 to support launch in Europe during FY24



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 markets



HIV self-testing increasingly being adopted by public health bodies around the world to scale up testing among key at-risk cohorts
Atomo has programs underway in Australia, the UK and discussions with US CDC pending



Atomo is now focused on further expansion of its HIV business and is seeking partners to support launch in remaining key markets, including the US and China, as well as assessing opportunities to expand the menu to include a HIV/Syphilis combo product



FIRST BLOOD BASED OTC PREGNANCY TEST TO MARKET*

The AtomoNOW rapid pregnancy test is a unique solution in a very large addressable market. This blood-based pregnancy test offers a number of significant advantages over traditional urine based rapid tests:

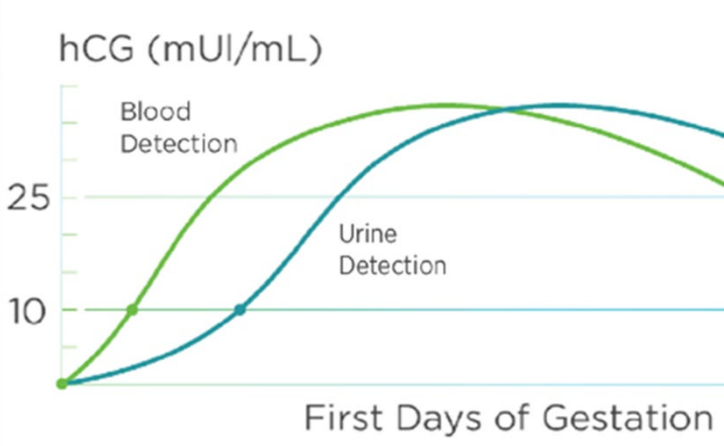
- **Earlier detection of pregnancy and more reliable in the early phases of pregnancy**
- **Can perform the test at any time of day** (rather than needing first flow with urine)

Key Selling Points	Product Promise	Customer Pain Point	Product Proof Point
Blood detects earlier than urine	hCG hormone appears earlier in blood than in urine	Customer wants to get their result as early as possible.	AtomoNOW uses blood to test for hCG levels in the body at 10 mIU/mL making it an ultra early pregnancy test compared to urine.
Higher accuracy at low levels of hCG	99.7% accuracy at 10mIU/mL, unlike urine which has an accuracy rate of 60-70% at this levels.	Customer wants results to be accurate and not have an incorrect result	AtomoNOW has been validated in clinical studies conducted in France and is CE Marked for sale in Europe
Test anywhere, anytime	Unlike Urine tests, you don't need the first morning's specimen to get an accurate result. As reliable after work as first thing in the morning	Customer wants to test straight away not wait until the next morning - urine tests used later in the day are less accurate	hCG in urine weakens throughout the day, while levels in blood stays constant meaning you can buy a test and use it straight away

* Developed in partnership with NG Biotech, the product is launched in France, the UK and Brazil, with Australian TGA approval anticipated in the coming months. US Pre-sub to FDA lodged in September 2023

We consistently see that approximately 1 in 5 pregnancy test purchasers would buy AtomoNOW™ #

This matches the proportion who feel very positive about the concept, the proportion who express that they are very interested in purchasing it (unpriced) and the proportion who say they will buy it at US\$20.



Independent survey of 300 women aged 18-45 in Australia who bought a pregnancy test in the last 12 months



ATOMO'S OEM TECHNOLOGY BUSINESS

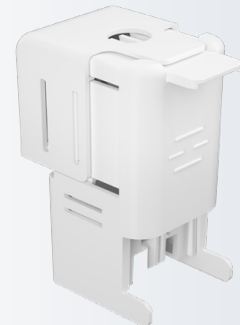
Atomo offers partners a broad range of unique products that fundamentally improve rapid testing



BLOOD TEST SOLUTIONS

A range of proprietary integrated blood test devices proven to reduce common errors with rapid testing and improve usability, especially with untrained self-test users

Commercialised across an increasing range of clinical applications

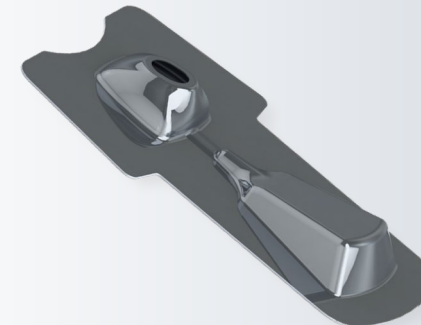


SWAB TEST SOLUTIONS

Portfolio of patents and device development that improve swab and saliva rapid testing

Supports a broad range of swabs with multiple test applications

Compatible with existing standard cassettes in market

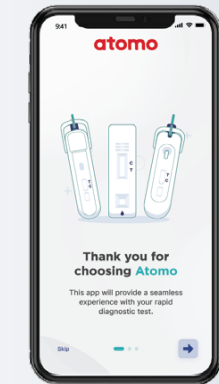


BLISTER SOLUTIONS

Direct supply opportunity to OEM device partners and POC cassette developers

Frangible seal delivers best in class precision and multi-stage reagent delivery

Co-commercialisation/license



DIGITAL HEALTH OFFERINGS

Video of user steps. Image Recognition to interpret results (removes user errors and improves precision)

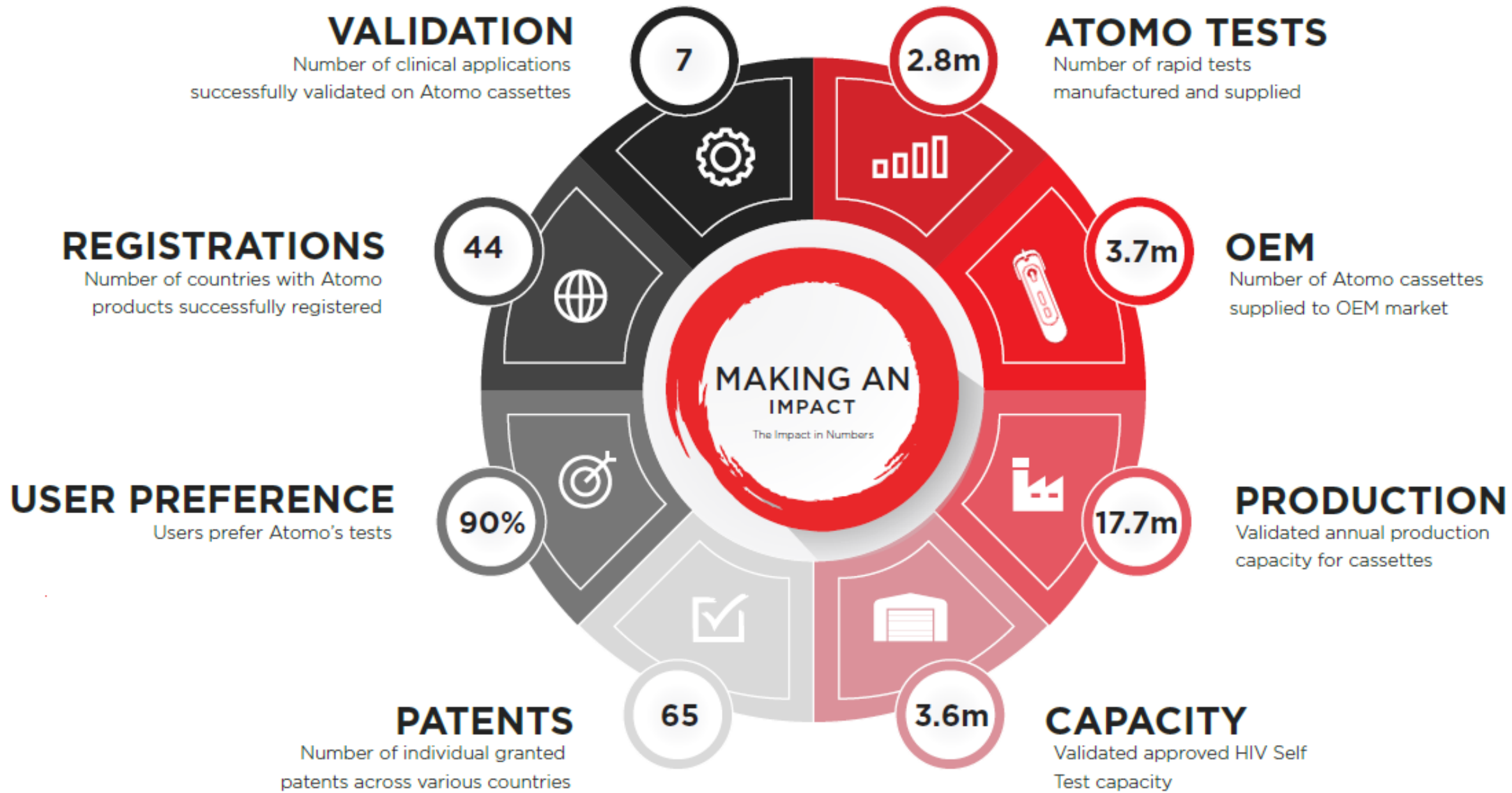
Semi-Quantitative results. Patented Blood delivery QC algorithm

- *Atomo's existing blood cassette partners have recommenced ordering Pascal after a hiatus during the COVID pandemic*
- *The Pascal device is now approved through a US FDA 510k in the US market providing a predicate for other potential partners to bring further tests to market in the US*



MAKING AN IMPACT

With experience in rapid testing technology, Atomo has runs on the board



STRATEGIC FOCUS FOR FY24 & FY25

The overarching 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 consumer self tests, via a number of emerging revenue streams

Continued growth of the HIV Self-Test business, through a focus on:

- Continued support of recently opened up pharmacy / retail channels in key developed markets
- Deployment into public health in developed markets, such as Australia and Europe
- Securing commercial arrangements to support US 'go to market' launch
- Taking control of more private sector markets in middle income countries, such as Columbia & Mexico, and securing better placed in-country commercial partners

Expanding the portfolio of finished tests that Atomo is able to market directly or supply to strategic channel partners:

- Launching the AtomoNOW pregnancy test in ANZ and progressing the regulatory submission in the US
- Securing regulatory approval and launching the AtomoNow iron deficiency (Ferritin test)
- Seeking to develop and commercialise tests to home monitor levels of Testosterone and of Vitamin D

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

- Support of existing partners rolling out Pascal supported tests globally
- Securing supply agreements for new partners and products on the back of recent regulatory approvals, entry into mainstream retail channels driving increased market awareness

