



ATOMO DIAGNOSTICS

(ASX:AT1)

EXECUTIVE SUMMARY

Atomo Diagnostics Limited is an innovative medical device diagnostics company supplying unique, integrated rapid diagnostic test devices and finished point-of-care rapid tests to global partners and consumers

<ul style="list-style-type: none"> ○ Company Overview 	<ul style="list-style-type: none"> ○ Atomo is a global company headquartered in Australia with commercial resources in the US, UK & Europe and a certified operations facility in South Africa ○ Point of Care Technology business in which Atomo's unique blood and swab test devices and components are sold to diagnostic companies for their own test applications ○ Point of Care Products business includes tests for HIV, ultra-early pregnancy and iron deficiency for point-of-care
<ul style="list-style-type: none"> ○ Best In Class Product 	<ul style="list-style-type: none"> ○ Best-in-class usability, accuracy and self-testing approvals: enhanced usability is key to unlocking regulatory approvals for blood testing in key markets, especially the US ○ Significant growth opportunity as the market continues to shift to decentralised and at-home testing post-pandemic ○ Existing rapid tests are complex with high error rates while Atomo products are unique, simple and reliable supporting approval and use in consumer markets where usability is critical to the adoption of decentralised testing driven by ease of use, speed and accessibility
<ul style="list-style-type: none"> ○ Globally Commercialised 	<ul style="list-style-type: none"> ○ Developed and launched the world's first integrated, blood-based HIV Self Test ○ Regulatory approvals including CE Mark for Europe, Australian TGA and prequalification by the World Health Organization ○ Registered in 46 countries worldwide with over 1.5 million units sold ○ Atomo and partner NG Biotech have developed a blood-based 'early detection' rapid pregnancy test launched in France, UK and Brazil, with Australia launch imminent and Europe and US to follow ○ Recent approval of FebriDX provides a predicate device for the US FDA, potentially shortening and de-risking the approval process for new tests on Atomo's platform
<ul style="list-style-type: none"> ○ Strong Product Development Pipeline 	<ul style="list-style-type: none"> ○ Targeting women's health and at-home wellness monitoring ○ Application to TGA for rapid hCG pregnancy test in process, target regulatory approvals and launch in Australia, NZ and Asia in CY23 and the UK/Europe in CY 24, the US to follow in CY24/CY25 ○ Blood based rapid tests being developed and commercialised for ferritin (iron deficiency) vitamin D with more clinical applications to come
<ul style="list-style-type: none"> ○ Capital Raise Overview 	<ul style="list-style-type: none"> ○ A capital raising of up to \$4.0m, comprising: <ul style="list-style-type: none"> ○ Placement of approximately \$1.25m at \$0.036 per share ○ Share purchase plan (SPP) to eligible shareholders to raise a further \$2.75m ○ The Company has also received commitments for an up to \$1.0m SPP shortfall placement if the SPP raises less than \$1.0m, ensuring a minimum of \$2.25m in gross proceeds will be received across the Placement and SPP ○ Funds raised will be used towards expanding and accelerating sales, marketing, business development and new product registration activities focusing on revenue generating activities ○ FY23 year-end pro-forma cash of \$10.4m¹ post capital raising

¹ Pro forma cash position as at 30 June 2023, plus capital raising proceeds, and excluding costs of the offer



WHO IS ATOMO AND WHAT DOES IT DO?

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 ferritin tests for POC and at-home self-test, 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 LEADS DISRUPTIVE INNOVATION IN RAPID TESTING

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



“The lancet would not be out of place in a 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

ISSUES WITH STANDARD RAPID TEST KITS

- COMPLEX:** Multiple components, too many steps, requires expertise
- HIGH ERROR RATES:** Difficulties securing 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

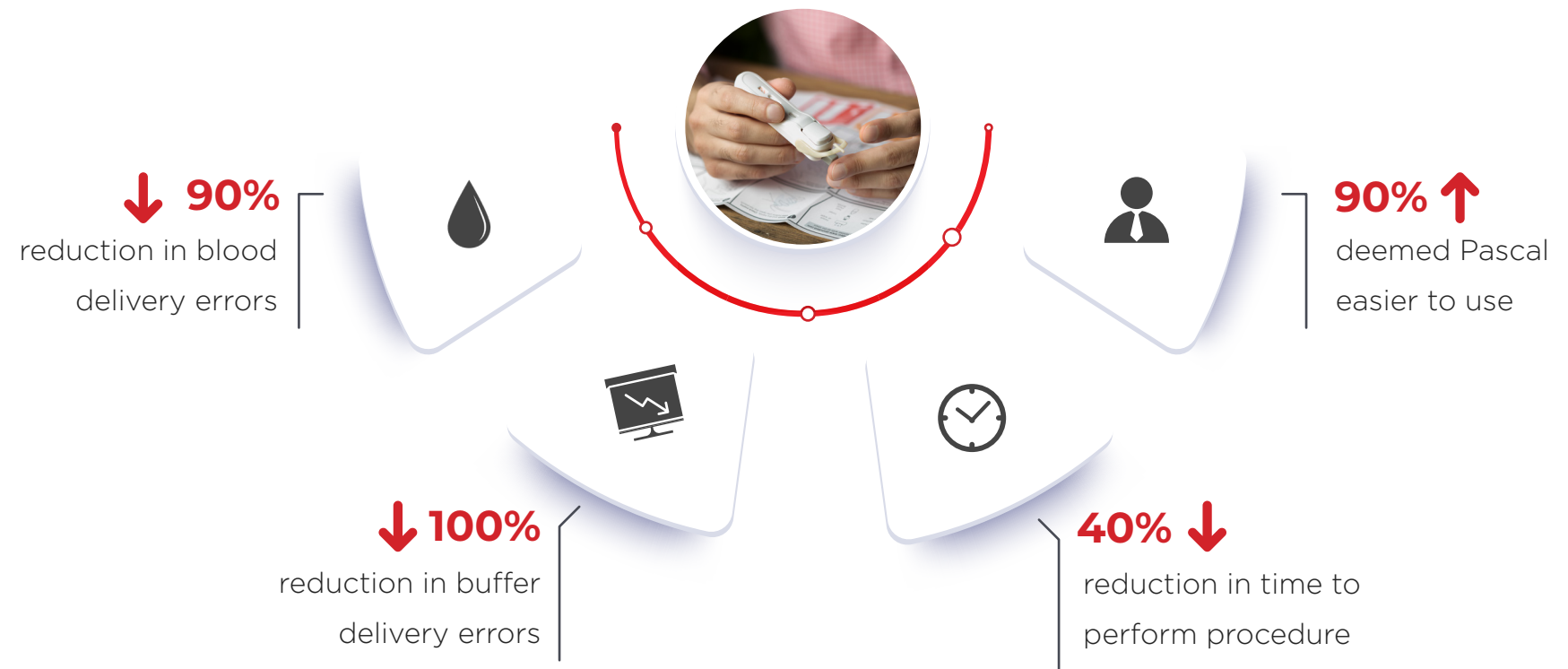
WHAT DRIVES ADOPTION OF RAPID TESTING¹



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.



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 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, with product anticipated to be supplied by Newfoundland into Tesco, Boots and SuperDrug



HIV self-testing is increasingly being used by public health bodies around the world to scale up testing with demand in both developed markets and global health expected to grow over the next 5 years



Atomo is now focused on further expansion of its HIV business and is seeking partners to support launch in remaining markets, including the US, Brazil, Mexico and China

* Excludes Professional Use tests sold



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

2023/24

2024 AND BEYOND

PREGNANCY



Atomo and partner NG Biotech have developed a blood-based 'early detection' rapid pregnancy test

Already launched in France, the UK and Brazil, **Atomo is targeting regulatory approvals and commercial launch in Australia & New Zealand in CY23**; and in Asia and the US in CY24, having received interest from go-to-market partners. Atomo's device enabled its partner to secure 510k clearance for their rapid test application

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 & OTHERS



Atomo is developing a quantitative test to regularly monitor vitamin D levels using its app with patented reader technology

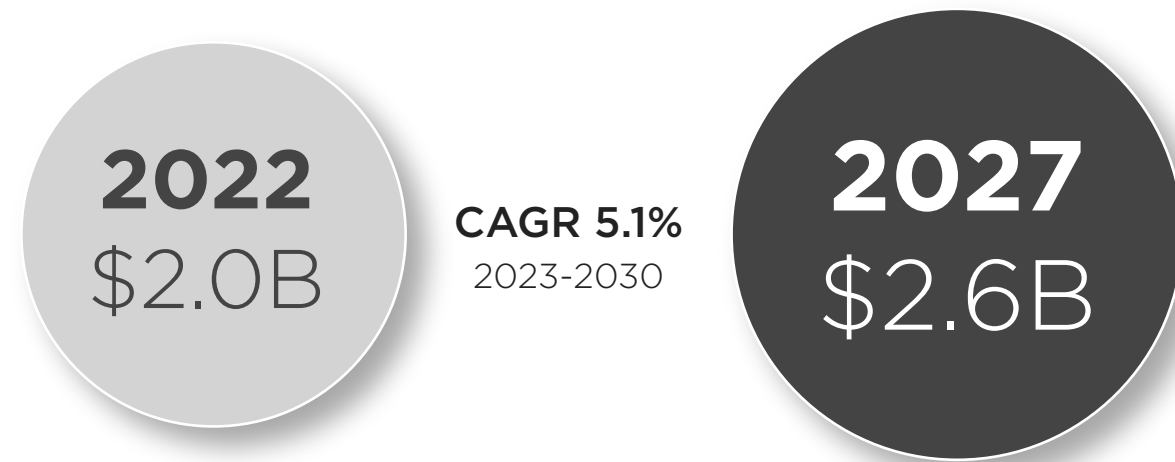
Atomo is initially targeting approval and launch in Australia, NZ, the UK and Europe in early 2025



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 SIZE¹ (REVENUE AUD²)



- The US, with around one-third of the global market share (2021), performs more than 30 million rapid pregnancy self-tests each year
- Increased focus on earlier pregnancy detection given recent changes to the US landscape for women's health
- 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

ATOMO'S OPPORTUNITY

- Atomo has experience in expanding distribution partnerships across professional-use and OTC retail channels
- Priority on approval and launch in Australia, the U.S. and Canada, with submission to TGA underway and approval anticipated later this calendar year, along with the commencement of U.S. clinical trials. The Australian pregnancy test market is estimated at more than 5 million tests annually
- Only one test provider has approval for a blood pregnancy test in the US (not CLIA waived, or OTC self-test approved)
- Atomo's pregnancy test partner, NG Biotech, seeing increased demand in Europe, as well as further expansion and sales including a recent product launch in Brazil and UK launch later this year

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

² USDAUD 1.48



ATOMONOW™ PREGNANCY TEST

The AtomoNOW™ Pregnancy Test is the only blood-based pregnancy test on the Australian market¹

BENEFITS

- 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

atomoNOW™ PREGNANCY TEST



¹ Subject to TGA approval



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



THE HOME TEST MARKET - RESPONDING TO CONSUMER DEMAND

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

newfoundland



ZSAN | amazon

Diagnostic Test Kit Range

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

Now Available

Quest Diagnostics™ 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.

	Food Sensitivity Comprehensive Test ★★★★★		Women's Health Test ★★★★★
	STD Test - Female ★★★★★		Metabolism Test ★★★★★

atomo

HOME ABOUT CONTACT SUPPORT FAQ HOW TO USE FOR CLINICS BUY NOW

Australia's Only HIV Home Test

Convenient, Accurate and Discreet

BUY NOW

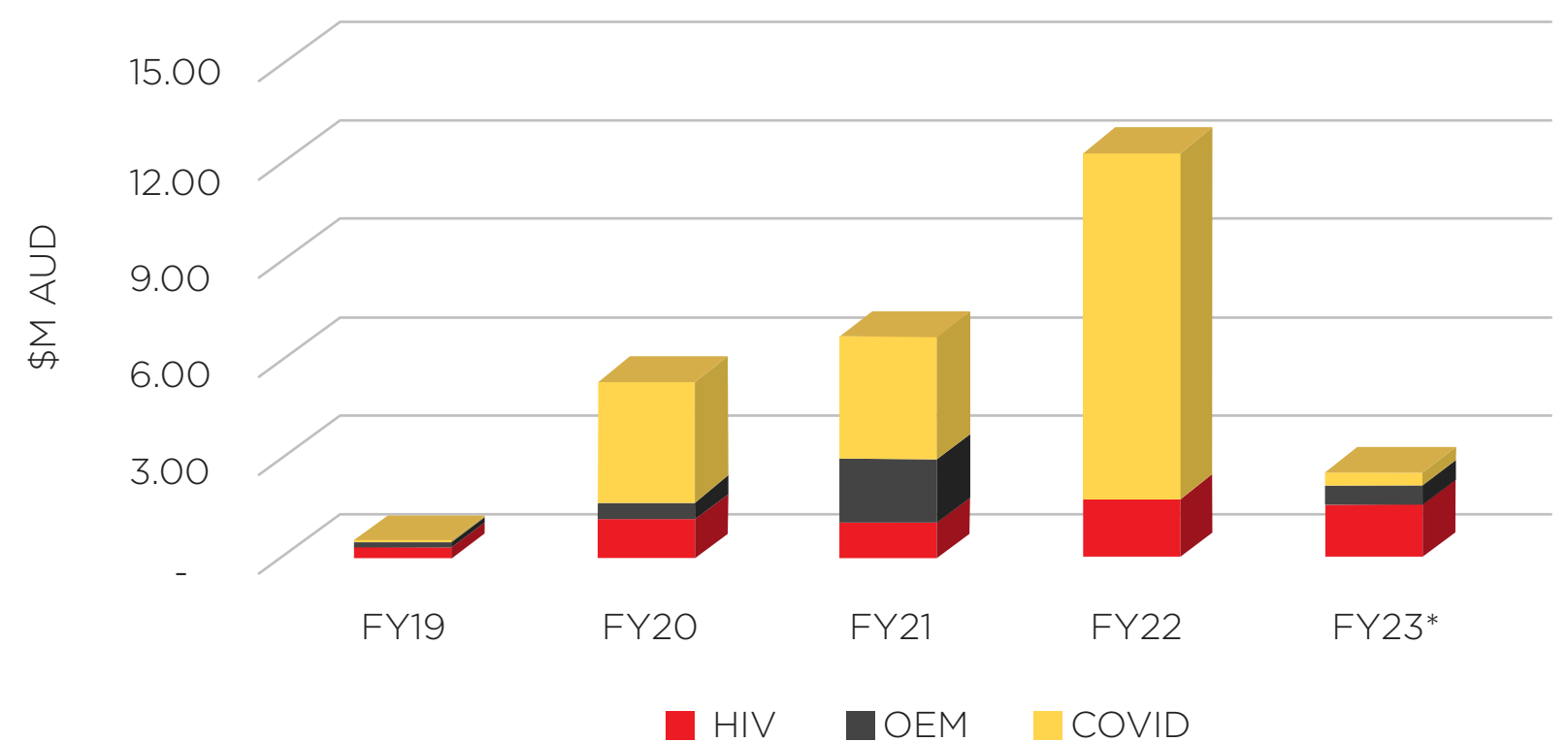
* The slide depicts general examples, not only specific Atomo Diagnostics products, customers or channels



KEY METRICS

- Early revenue from first commercialisation of HIV Self Tests in the South African domestic market in FY19
- Non-COVID revenue growth impacted during FY20-FY22 by diversion of funding and attention to COVID-19 testing
- Pivot to COVID-19 testing led to significant contribution to revenues during FY20-FY22
- FY23 return to quarterly growth in non-COVID-19 revenue
- FY23 year end cash of \$6.4m* and no debt
- Roll out plan for new products in FY24 and FY25 to drive additional growth beyond HIV and OEM

Annual Revenue (Inc. COVID-19)



Atomo anticipates reaching breakeven operating cashflow using its current capacity and resources, with target margins at 50% and steady state opex of around \$750k per month. After that, the company is leveraged to profitability with further growth not requiring a significant increase in headcount or investment

*Unaudited



KEY INVESTMENT HIGHLIGHTS

- Atomo operates in an **expanding global rapid testing market** driven by significant industry and consumer tailwinds
- **Atomo has patent protected user friendly testing technology**, with multiple OEM contracts, a strong pipeline and emerging channel partner demand
- Best-in-class usability offers the opportunity for **first approved OTC blood tests in the US market**, starting with pregnancy with the company moving quickly towards submission for FDA approval
- **Highly regarded finished products with regulatory approval for high volume applications**, including HIV screening and blood-based early pregnancy detection
- Well progressed with **commercialisation of a range of home tests** with channel partners indicating demand, driving further revenue growth and diversification
- **Regulatory certified, low cost manufacturing in place** and easily scaled to significant operational leverage and margin growth in the near term (without further capital expenditure)
- Atomo has completed its intensive manufacturing CapEx phase - **future investment focused on commercialising new products, driving revenue growth and delivering investor returns**
- De-risked US market entry with recent **510(k) approval** obtained by Lumos for FebriDx product on the Atomo proprietary integrated Pascal device



CAPITAL RAISING STRUCTURE

<ul style="list-style-type: none"> ○ Placement 	<ul style="list-style-type: none"> ○ Placement to raise approximately \$1.25 million under the company’s existing placement capacity per LR7.1 (“Placement”) ○ Approximately 35.0 million new fully paid ordinary shares in AT1 (“New Shares”) to be issued under the Placement, representing approximately 6.1% of AT1 current shares on issue
<ul style="list-style-type: none"> ○ Offer Price 	<ul style="list-style-type: none"> ○ New Shares issued under the Placement will be issued at a price of A\$0.036 per new share (“Offer Price”), representing a: <ul style="list-style-type: none"> ○ 30.8% discount to the last close price on 10 July 2023 of \$0.052 ○ 53.5% discount to 5 trading day VWAP up to and including 10 July 2023 of \$0.077
<ul style="list-style-type: none"> ○ SPP 	<ul style="list-style-type: none"> ○ The Company intends to offer eligible shareholders the opportunity to participate in a Share Purchase Plan (“SPP”) and apply for up to \$30,000 of New Shares, to raise a further \$2.75 million ¹ ○ The SPP will be offered at the lower rate of: <ul style="list-style-type: none"> ○ \$0.036 per New Share, being the price paid under the Placement; and ○ 2.5% discount to the VWAP of shares traded on the ASX during the five trading days up to the closing date of the SPP, rounded to the nearest half cent ○ Record date for determining eligibility for the SPP is 7.00pm Wednesday, 12 July 2023 ○ Further details in relation to the SPP including the timetable will be provided to eligible shareholders in an SPP booklet expected to be released following the Placement ○ The Company has received binding commitments for a placement of up to \$1.0m at the same price as the SPP in the event that less than \$1.0m is raised under the SPP, ensuring a minimum of \$2.25m in gross proceeds will be received across the Placement and SPP. The commitment will be reduced (pro rata) to the extent of the funds raised under the SPP. Any shares issued pursuant to such commitment will be raised without disclosure to a professional/sophisticated investor and within the Company’s placement capacity under Listing Rule 7.1.
<ul style="list-style-type: none"> ○ Ranking 	<ul style="list-style-type: none"> ○ The New Shares issued under the Offer will rank equally with existing Atomo shares on issue on the relevant issue date
<ul style="list-style-type: none"> ○ Lead Manager 	<ul style="list-style-type: none"> ○ Bell Potter Securities Limited

¹The Company reserves the right to accept oversubscriptions under the SPP



USE OF FUNDS

Atomo's focus is on expanding and accelerating its sales, marketing, business development and new product registration activities to focus on revenue generating activities and growth. The primary objectives are:

- Commencement of the FDA registration process for the hCG Pregnancy Test in the US
- Finalising the registration and launch of the Atomo hCG Pregnancy Test in APAC, which is in the advanced planning stage
- Optimising operations for the production of Iron Deficiency Test in the Atomo South African facility, and registering and launching the product in ANZ and Europe
- Continuing to develop OEM opportunities for the Atomo platforms, particularly in the US given the recent 510k approval for FebriDx on the Pascal platform
- Ongoing product pipeline development

Given the installed production and manufacturing capacity, there is minimal capex forecast over the period

USE OF FUNDS	\$
hCG Pregnancy Test sales and marketing (ANZ/US)	1.6m
Iron Deficiency Test registration and commercial activity (ANZ/UK and Europe)	350k
POC Technology (OEM) business development	350k
Product development (app, digital, Vitamin D)	500k
Working capital	1.2m
Total	4.0m



TIMETABLE

EVENT ¹	2023
Record Date for the SPP	7.00pm Wednesday, 12 July 2023
Capital Raising announced and trading halt lifted	Thursday, 13 July 2023
SPP Offer opens	Tuesday, 18 July 2023
Settlement of the Placement	Tuesday, 18 July 2023
Allotment of New Shares under the Placement	Wednesday, 19 July 2023
SPP closes	Tuesday, 1 August 2023
Allotment of New Shares under the SPP	Tuesday, 8 August 2023

This announcement was authorised by the Managing Director and CEO

¹The above timetable is indicative only and subject to change. Subject to the requirements of the Corporations Act, the ASX Listing Rules and any other applicable laws, Atomo in consultation with the Lead Manager, reserves the right to amend this timetable and withdraw the offer at any time



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