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atomo

FY21 Results Presentation

27 August 2021

ATOMO DIAGNOSTICS LIMITED | (ASX: AT1)

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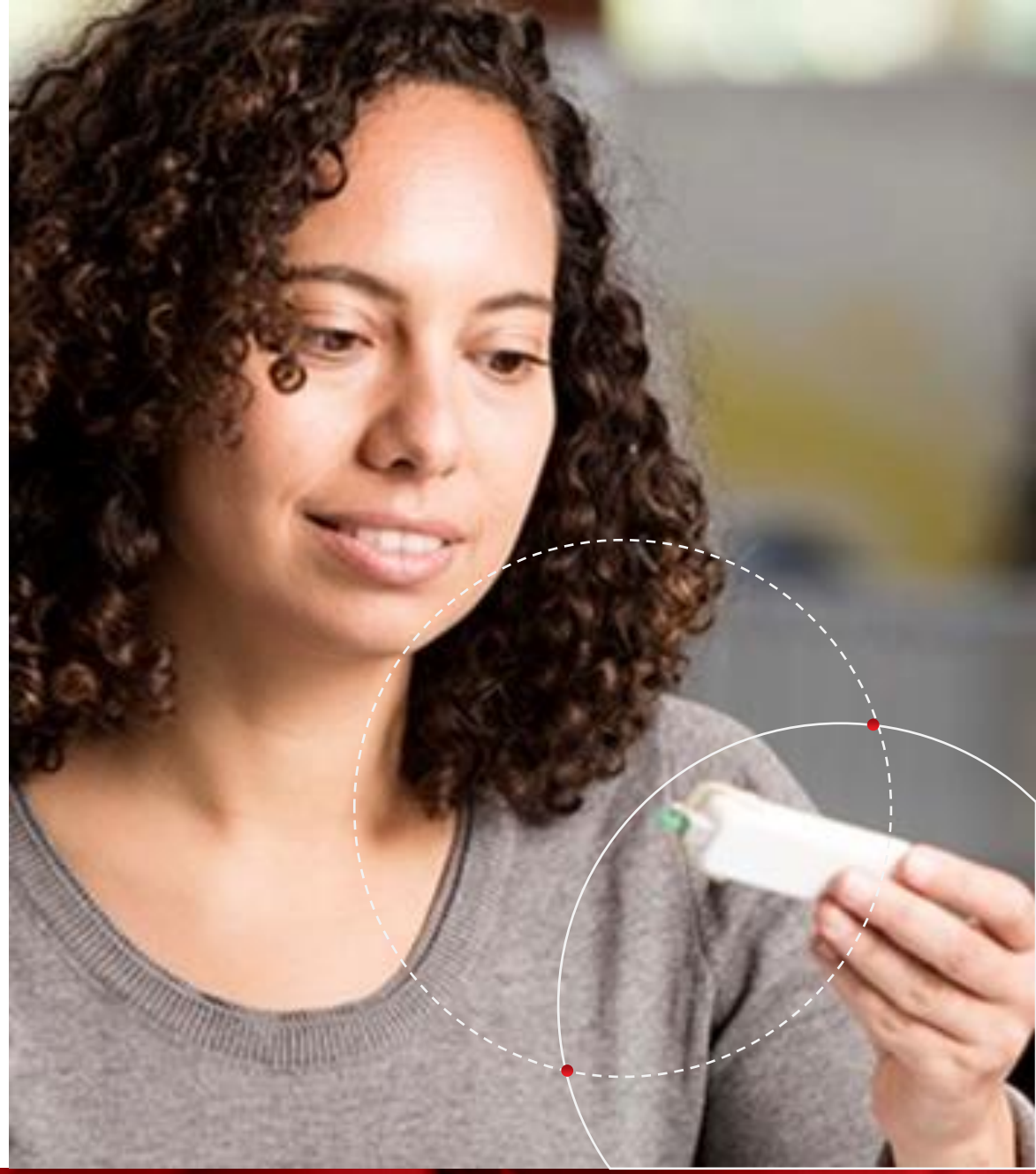
INTRODUCTION

Atomo Diagnostics Limited (ASX: AT1) is an innovative medical device company supplying unique, integrated rapid diagnostic test (RDT) devices to the global diagnostic market

Headquartered in Australia with global operations, Atomo develops, manufactures and supplies innovative, patented devices that simplify rapid testing

Increasing market traction in Europe, the US and most recently Australia, plus many Global Health markets selling approved Atomo finished tests to healthcare distributors and devices to diagnostic customers (OEM)

Atomo has grown customer sales revenue 25% year on year, to $6.7m for FY21 and continued to invest for growth through increased production capacity and new solutions



KEY FY21 HIGHLIGHTS

- **Atomo COVID-19 rapid Antibody and Antigen tests** – Added by the TGA to the ARTG* in H1 FY21 for supply in Australia. Circa. 50k, primarily antibody test units sold in H2 FY21. Antigen test demand commenced in Q4, stepping up very significantly in Q1 FY22
- **Access Bio Inc. (USA) agreement and supply** - Partnership signed Q1 FY21 for COVID-19 antibody RDT tests on Atomo platform in the North American market. Initial product delivered Q3 FY21, in advance of US FDA EUA which was granted late Q4 FY21
- **Unitaid (HIV)** - Global health agreement signed between Mylan (Viatris)/Atomo and Unitaid in Q4 FY21 for access to Atomo's HIV Self Tests in more than 135 countries. Initial orders commenced with first supply in late Q4 FY21 and expanding into Q1 FY22
- **OEM business** – Ongoing technical and commercial engagement progressing with several leading multinational diagnostics companies seeking access to Atomo's rapid blood test platforms and its proprietary functionality for non-blood test applications
- **US market entry –** Business development/commercial resourcing and local entity infrastructure currently being established to support expanded engagement in the US
- **New product development** - Atomo commences development of first non-blood rapid test platform in Q4 FY21 to expand its portfolio across growing point-of-care markets
- **Financials** – Sales growth of 25%, cash receipts of ~$8m and cash at bank of $18m

** TGA: Therapeutic Goods Administration, ARTG: the Australian Register of Therapeutic Goods - administered by the TGA*

FY21 DELIVERABLES – PROGRESS ON TRACK

COVID-19	DELIVERED
✓ North American deal with US Co. Access Bio	Q1 FY21
✓ AtomoRapid COVID-19 professional use test TGA Approval (Australia)	Q1 FY21
✓ AtomoRapid COVID-19 professional use test to be launched in Australia	Q2 FY21
✓ Commence supply of Galileo to Access Bio for their CareStart COVID-19 rapid Antibody test in the US market	Q3 FY21
✓ Regulatory approval by the FDA via EUA for the CareStart COVID-19 test for supply in POC settings in the US	Q4 FY21
HIV	
✓ AtomoRapid HIV professional use test to be launched in Australia	Q3 FY21
✓ Expansion of HIV capacity in Cape Town to support growth – success in securing Unitaid agreement	Q3 FY21
OPERATIONS	
✓ Total device capacity to be increased to 1.3m per month	Q3 FY21
✓ US business and dedicated resources being set up	Q4 FY21 & Ongoing
DEVELOPMENT	
Next Atomo Finished Product to be developed – Saliva test device in development	Ongoing
✓ The Elion Self Test Device to be launched as an OEM product for the OTC Consumer market	Now Ready
✓ Digital eHealth solution to be implemented to support OEM and Atomo product expansion	Prototype Ready

COVID-19 RAPID TESTING IS HERE TO STAY

COVID-19

- Demand for Atomo platforms for use in COVID-19 antibody testing in FY21 with 1.1m units sold to NG and Access Bio for European and North American markets. Access Bio secured FDA EUA (POC) for their antibody test on the Atomo platform in Q4 FY21
- Atomo COVID-19 antibody and antigen tests listed by the TGA on the ARTG, positioning Atomo locally as demand has grown in Australia towards the end of the financial year and accelerated significantly in Q1 FY22
- A significant Delta variant outbreak in Australia has resulted in a recent change of position from government. Now seeing widespread public health acceptance and market adoption of rapid antigen testing across key sectors

COVID-19 Business Performance (FY21)

- ***COVID-19 Sales Revenue - $3.68m***
- ***COVID-19 OEM Units Sold – 1.1m***
- ***COVID-19 Test Products Units Sold – 50k***

Revenue drivers in the COVID-19 business:

- A robust commercial agreement secured for the US market
- Surge in demand in Australia for antigen tests since July seeing Atomo sell substantially more COVID tests in the first two months of FY22 than all of FY21
- More than 50 customers now using Atomo's antigen tests in Australia across a broad range of private and public sectors
- Very significant increase in product manufacturing activity to support unprecedented customer demand

HIV TESTING – GLOBAL HEALTH UNDERPINS GROWTH

HIV Self-Test

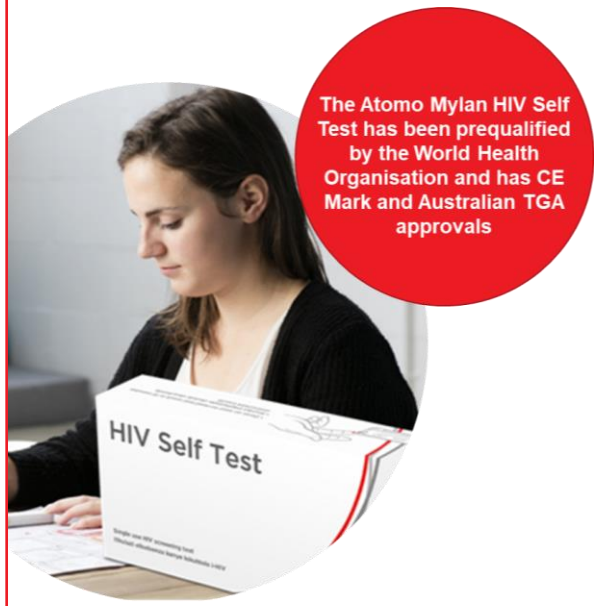
- Atomo's HIV self-test is the only HIV self-test approved in Australia (TGA). Also approved in Europe (CE Mark) and prequalified by the World Health Organisation (WHO)
- Atomo supplies Viatris (Mylan) with HIV self-tests. Agreement covering more than 135 countries and rollout expanding
- Atomo actively assessing opportunities to partner in the rapidly growing PrEP and on-line channels in developed markets
- HIV self-test demand in LMIC markets anticipated to more than double over the next 5 years*

HIV Business Performance (**FY21**)

- ***HIV Sales Revenue - $1.08m***
- ***HIV Units Sold - 268k***

Drivers of Growth in the HIV Business:

- One of only two test providers in the Unitaid global procurement program; expected to lead to sustained growth over the next five years
- Growing list of countries where the Mylan HIV test is now registered and being promoted by Viatris
- Product commercialisation agreements currently being sought for two leading markets, the US and China



*Johnson C et al (2020). HIV self-testing market forecasting. World Health Organization - Diagnostic Manufacturer Meeting. Power Point presentation (virtual meeting). 20th October 2020.

STRENGTHENING OEM INTEREST POST-PANDEMIC

Strategic Partnership Journey

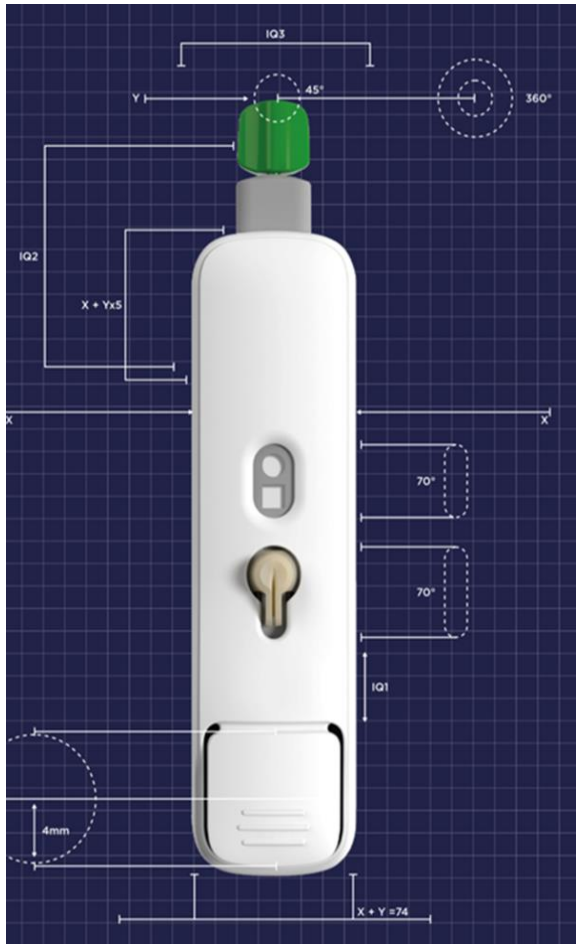
- Initially Atomo entered into OEM supply agreements with a number of early adopters that have proven the utility, marketability and regulatory capabilities of Atomo's platforms
- With this market validation and a expanded supply capacity, Atomo is now in discussions with a number of leading diagnostic multinationals interested in accessing Atomo's platforms and IP backed rapid test functionality
- Atomo is increasingly seeking to co-develop new rapid test solutions covering multiple sample types in partnership with the world's leading diagnostic companies

OEM Business Performance (FY21)

- ***OEM Sales Revenue – $1.98m***
- ***OEM Units Sold – 1.1m***

Drivers of Growth in the OEM Business:

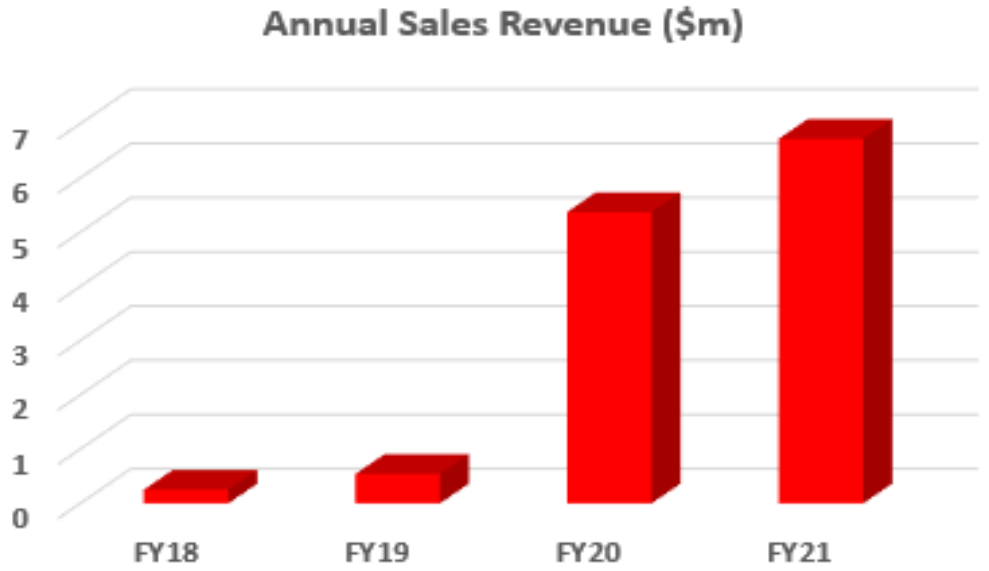
- Increasing recognition of Atomo's products via global health success and US FDA approval for a US made test on Galileo
- Installed production capacity of 1.3m devices per month supports growing customer demand
- Establishing dedicated US team to support the OEM market and secure channel partners in key RDT market segments



FY21 – PROFIT AND LOSS

AUD	FY21 ($m)	FY20 ($m)	Variance (%)
Revenue	**6.72**	**5.37**	**25%**
Cost of sales	(3.30)	(2.17)	52%
Gross Profit	**3.42**	**3.19**	**7%**
Gross Margin	**51%**	**60%**	
Other income	0.81	0.84	(4%)
Employee benefits expense	(3.81)	(2.97)	(28%)
Foreign exchanges gains/(losses)	(0.41)	(0.56)	27%
Research and development costs	(0.82)	(0.70)	(17%)
Professional fees expense	(1.79)	(0.93)	(92%)
Other expenses	(2.19)	(1.27)	(72%)
Underlying EBITDA^	**(4.79)**	**(2.38)**	**(101%)**

- As higher volume OEM and HIV business contributed more to the overall product mix during FY21 when compared to FY20 where higher margin COVID-19 business accounted for more revenue, the blended gross margin across the business moved from 60% to 51%
- Underlying EBITDA loss was higher as the business continued with global expansion and investment; employee headcount grew in addition to spend in regulatory & commercial advisory



- Revenue increased by **25% to $6.7m**, driven by:
  - strong momentum in customer demand for the Group's COVID-19 point of care antibody & antigen testing devices
  - the growth of Other OEM business in Europe and US
  - multi-year partnership within HIV Self-test with Viatris

FY21 Revenue comprises:

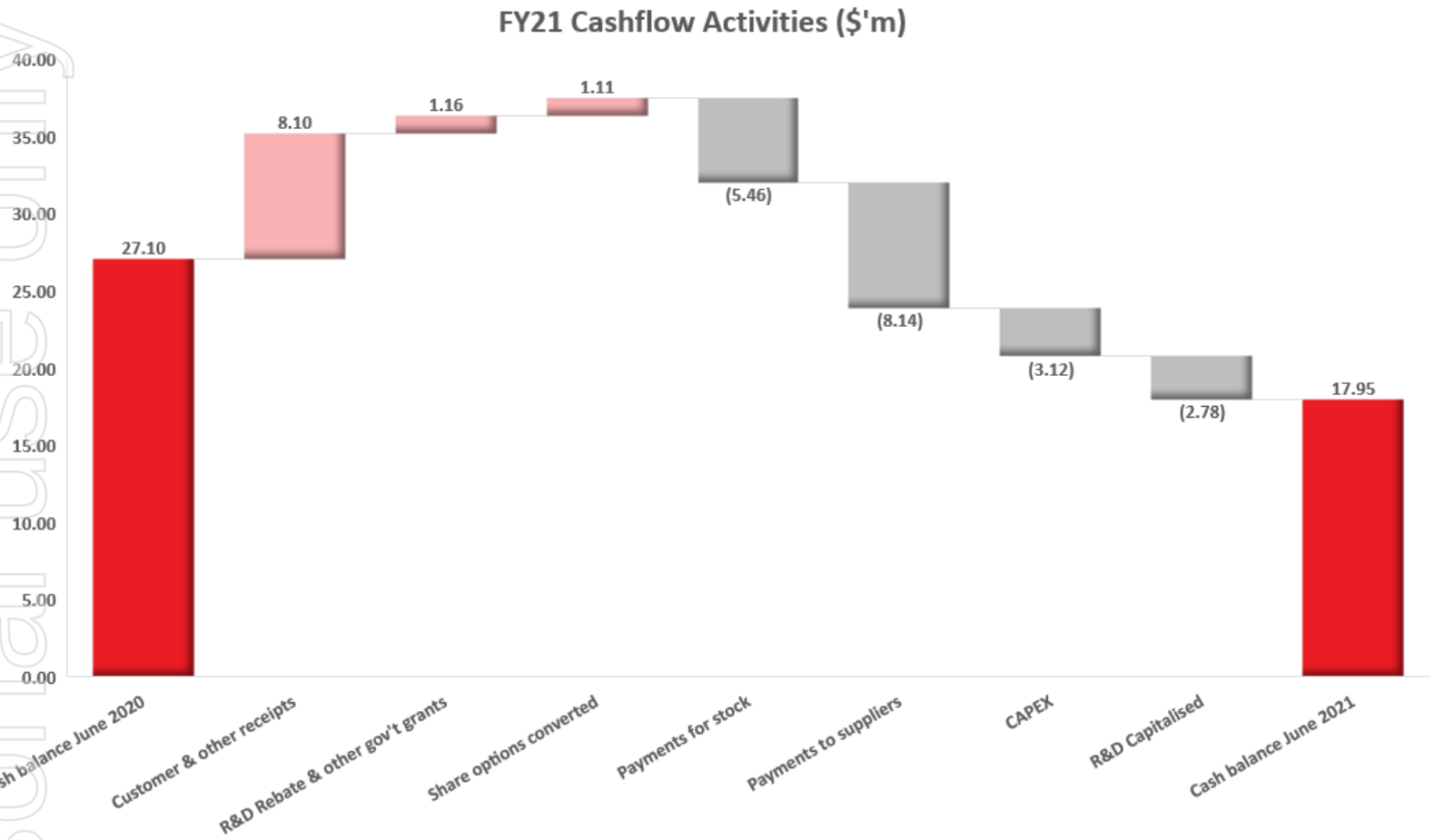
- COVID-19 related $3.7m
- HIV $1.1m
- Other OEM $2.0m

FY21 –BALANCE SHEET

AUD	FY21 ($m)	FY20 ($m)
Cash and cash equivalents	17.95	27.10
Trade and other receivables	4.49	4.76
Inventories	3.04	1.21
Property, plant and equipment	3.69	1.45
Intangible assets	3.00	1.52
Other assets	0.07	0.06
Total assets	**32.24**	**36.10**
Trade and other payables	1.78	1.30
Other liabilities	0.37	0.32
Total liabilities	**2.15**	**1.62**
Net Assets	**30.09**	**34.48**

- Cash balance of $17.95 million as at 30 June 2021
- Trade receivables & payables continues to remain within expectations
- Inventories continue to ramp up to supply into OEM, HIV and COVID-19 OEM and Finished Product channels
- Continued strong investment in production capacity, with significant expansion of production lines for device manufacturing and build out of next generation blister machine to support Pascal, Elion and future products utilising automated buffer reagent integration
- Total R&D spend for FY21 of $3.5m:
  - $800k expensed through the profit and loss statement
  - $2.7m capitalised to the balance sheet
- Net asset position of $30m

FY21 – CASHFLOW ACTIVITIES



- Cash receipts of $8.1m for the year underpin continued investment in growth
- Cash outflows predominantly consisting of:
  - revenue generating investments; payments for inventory of $5.5m to meet demand from customers in OEM, COVID-19 and HIV
  - expansion of Atomo facilities in South Africa to underpin HIV production expansion
  - investment in tooling for additional device capacity
  - spend on device R&D and next-gen blister machine which are core proprietary assets in the Atomo portfolio
- Strong year-end cash position of $17.95m to drive investment in commercial expansion, including very strong local demand for COVID-19 antigen tests, plus new product innovation beyond blood testing

ATOMO'S STORY

Atomo's founder, John Kelly, came into diagnostics with a track record of radically transforming the user experience and health outcomes in the medical device field. By arming consumers with simple to use, fast, accurate diagnoses and a seamless pathway to treatment, Atomo empowers patients to live healthier, more informed lives and makes healthcare more accessible.

2016

Atomo receives grant from Bill & Melinda Gates Foundation to develop a best-in-class HIV self-test

2017

Atomo partners with NG Biotech for the global sale of a high sensitivity blood-based pregnancy test

2018

Atomo announces partnerships for HIV self-testing with Mylan and Owen Mumford, covering more than 100 countries

2019

Mylan / Atomo HIV self-test receives prequalification by the World Health Organization (WHO)

2020

Pandemic breaks: Atomo announces agreements with NG and Access Bio to commercialise rapid COVID-19 tests and secures TGA approvals

2021

Mylan / Atomo HIV self-test selected for the Unitaid global tender program

Access Bio secures FDA EUA for the antibody test on Atomo's Galileo platform

STANDARD RAPID TESTING: OFF PATENT & COMPLEX

Traditional ‘bits in a box’ Lateral Flow kits

Standard rapid test ‘bits in a box’ test kits typically contain multiple components adding complexity with user errors common and regulatory challenges for home testing

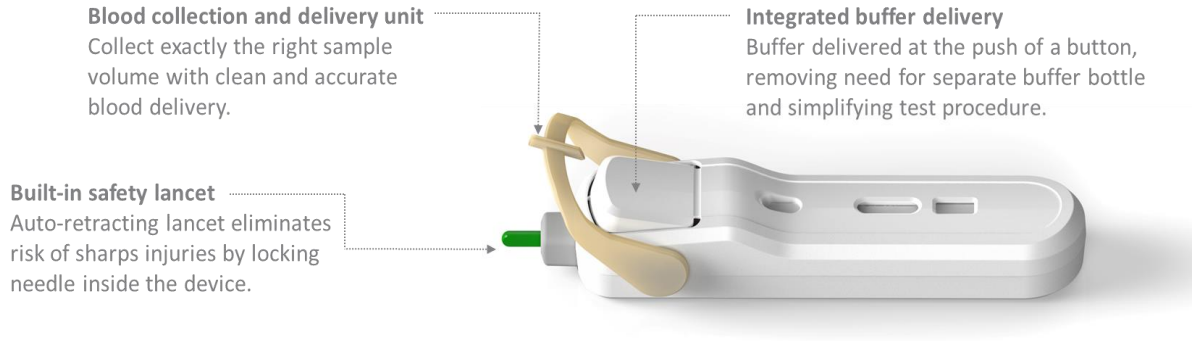
10%
Error rates when used by healthcare professionals

30%
Error rates when used by untrained self-test users

- Rapid Lateral flow based technology was commercialised more than 30 years ago and is now broadly off patent
- This has resulted in low barriers to entry with many players entering the market across a broad range of clinical applications as seen most recently with COVID-19
- This has led to the market experiencing significant commoditisation of RDT products, with little differentiation outside of the chemistry in the assay (itself largely unknown to end users)
- Prior to Atomo identifying a significant unmet need in the market, little real development effort and innovation had gone into improving usability, reliability and utility of the rapid test procedure itself
- These standard kits are not intuitive and user satisfaction is generally low, especially in consumer health - self test applications

ATOMO'S SOLUTIONS – INTEGRATION & ELEGANCE

For Atomo, a good lateral assay test is only the starting point to a good diagnostic test… ***if it can't be easily used in real-life settings user-driven error rates undermine the test itself***



Pascal Test – supports professional and self test applications

Elion Self Test – the most user friendly rapid blood test available

1. Prick finger
2. Fill sample well
3. Press activation button

DaVinci Combo Test – two strips in a single rapid test *

- *DaVinci can deliver different sample volumes to each test strip and also offers integrated blister reagent functionality*

REGULATORY APPROVALS

Australian TGA

- The Atomo COVID-19 Antigen Test is approved by the TGA **(ARTG 346587).**
- The AtomoRapid Covid-19 (IgG/IgM) Rapid Antibody Test is approved by the TGA **(ARTG 341411).**
- The Atomo HIV Self Test is the **only approved HIV self test approved** by the TGA **(ARTG 311989).**
- The Atomo HIV Professional Use Test is approved by the TGA **(ARTG 347510).**

US FDA

- The CareStart™ COVID-19 Antigen Test, manufactured by Access Bio, Inc. has been granted FDA-EUA. The Atomo COVID-19 Antigen Test and the CareStart™ COVID-19 products are identical products with identical diagnostics performance but are just branded differently.
- Access Bio has been granted FDA-EUA (CLIA Certificate of Waiver for POC use) under the brand name **CareStart™ EZ COVID-19 IgM/IgG** for a COVID-19 antibody test that uses Atomo's Galileo platform.

CE-Marked Products

- Atomo has multiple CE-marked and Atomo / OEM-branded rapid blood test products, including its award-winning HIV products.
- All Atomo HIV products have undergone full conformity assessment (not self-declared) through BSI (Notified Body Number: 2797) and all batches are tested by a BSI reference laboratory prior to batch release.

WHO Prequalification

- The Atomo HIV Self Test is the only integrated blood based lateral flow rapid test prequalified by the World Health Organisation.
- Atomo was one of two tests that was selected by Unitaid to expand access to HIV self-testing in 135 eligible countries.
  To date, Unitaid investment has resulted in 5 million kits being distributed, with 21 million kits set to be procured by countries between 2020 and 2023.

ROBUST GLOBALLY PROTECTED IP POSITION

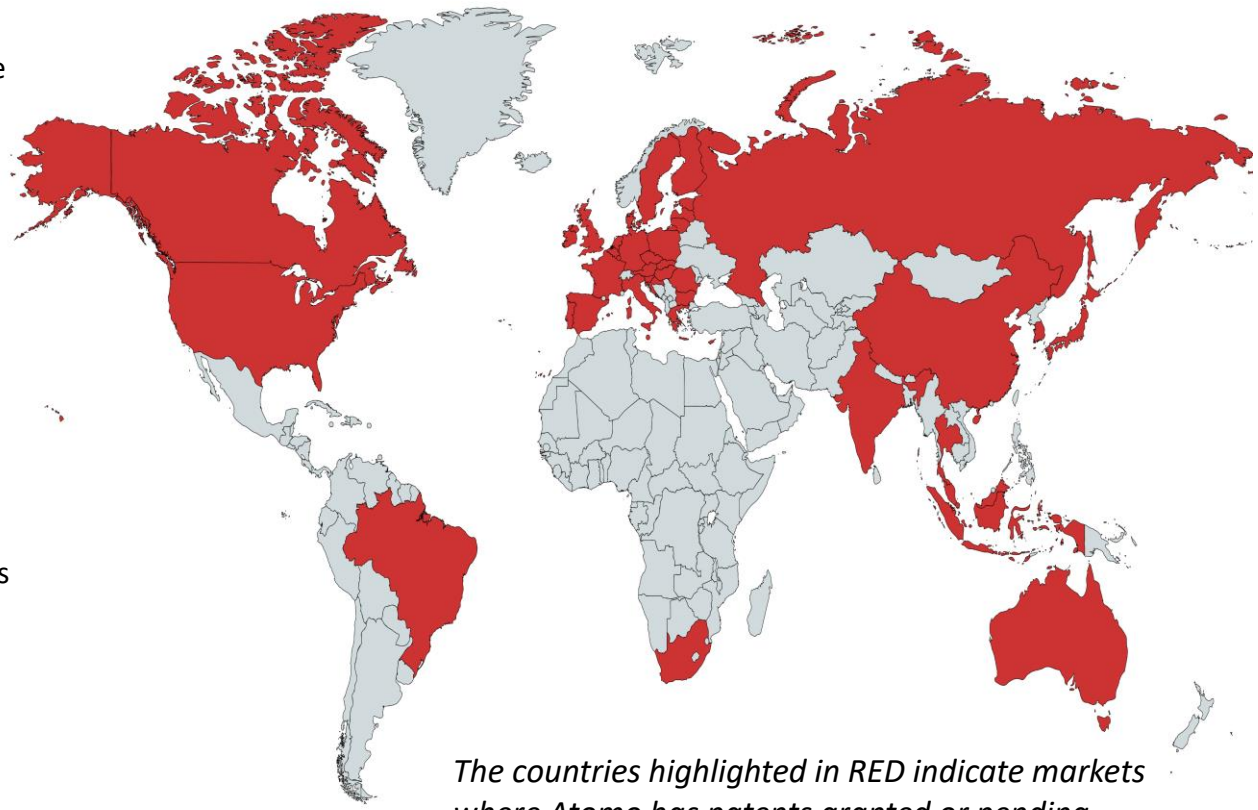
Family 1: Diagnostic System PCT/AU2011/000315
Relates to an integrated test system incorporating lancet, test, and internal buffer reservoir. The system is such that buffer is brought into contact with the test component only after the sample has been delivered to the test.

Family 2: Sampling Assembly PCT/AU2011/001321
Relates to the mechanism of the sample (blood) collector, so that a controlled volume is collected and retained by the device and then delivered to the test component. Further IP covers the additional feature of an interlock to prevent buffer release prior to sample delivery.

Family 3: Fluid Control in Integrated Testing Devices PCT/IB2014/066219
Relates to the functioning of the fluid delivery system and includes a control vessel (well) into which the buffer is first discharged before being released onto the test component, allowing for an efficient delivery and a controlled flow rate.

Family 4: Integrated Fluid Module and Test Device PCT/AU2016/051134 Relates both to how to reliably manufacture the reservoir with its associated frangible seal, and to details of the structure, particularly of the module with the reservoir and delivery vessel (well) and its interaction with the test unit.

Family 5: Integrated Blood Testing Device PCT/AU2018/051114
Relates to several inventions, including a test unit in which operating the actuator causes both the buffer to be released and the blood to be conveyed to the test component in the same action; and also to the interlock between the lancet and the actuator, so that the actuator is operative only after the lancet has been fired.

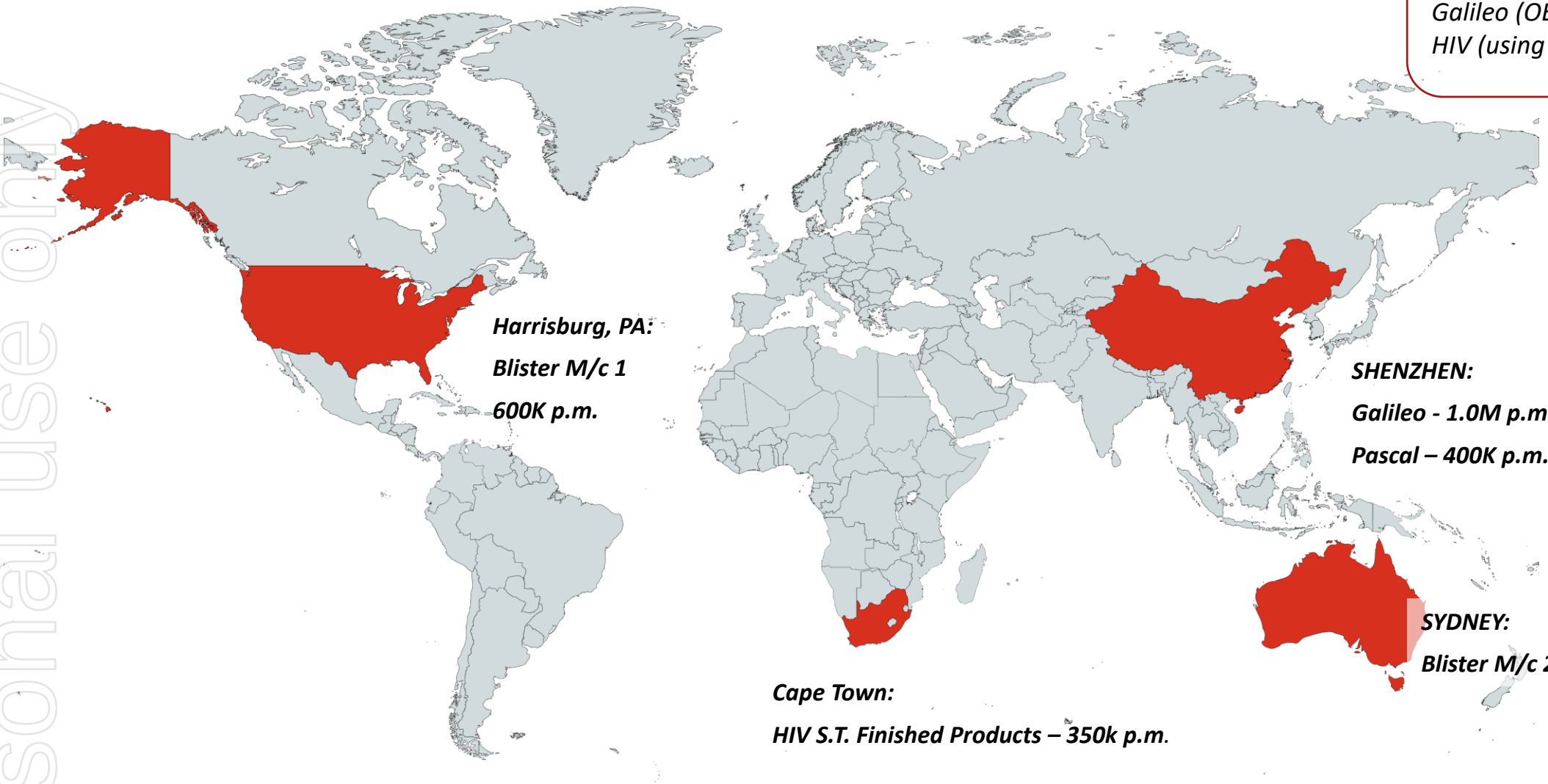


The countries highlighted in RED indicate markets where Atomo has patents granted or pending.

ATOMO OPERATIONS (END OF 2021)

PRODUCT CAPACITY:

Pascal (OEM) – 400K p.m.
Galileo (OEM) – 1.0M p.m.
HIV (using Galileo) – 350K p.m



Harrisburg, PA:

Blister M/c 1

600K p.m.

SHENZHEN:

Galileo - 1.0M p.m.

Pascal – 400K p.m..

SYDNEY:

Blister M/c 2 - 750k p.m.*

Cape Town:

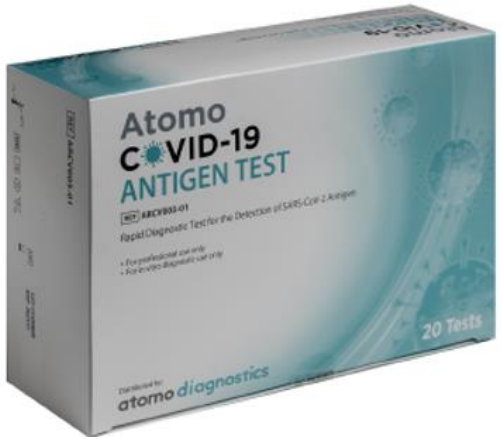
HIV S.T. Finished Products – 350k p.m.

** Blister machine v2.0 currently being completed – due by end of 2021*

ATOMO – POSITIVE IMPACT IN THE COMMUNITY

"We are proud of our initiative to introduce rapid antigen testing in July 2021. As a result of using Atomo Rapid testing, which the Government is soon introducing into high-risk settings, we've been able to support people to say goodbye to loved ones, facilitate the safer admission of residents from hospital, enabled the safe entry of emergency and essential contractors, as well as ensuring all care and clinical agency staff are rapid tested before entry into our homes."

Southern Cross Care NSW&ACT



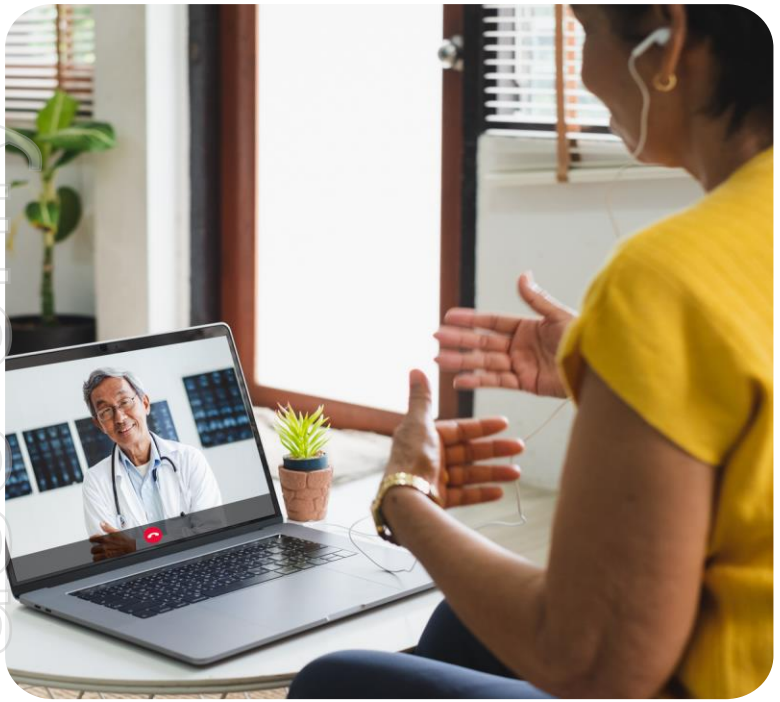
"Sadly, stigma and embarrassment still prevents many people testing for HIV. The arrival of this self testing device is a critical step in removing a barrier to people knowing their status"

Australian Federation of AIDS Organisations

"Super easy quick test, top instructions and quickly implemented."

HIV Self Test User, Germany, Amazon

FY22 - A NEW RAPID TEST LANDSCAPE



In the US, telehealth as a share of medical consults went from 0.2% pre pandemic to now accounting for ~6% of all consults, representing segment growth of 3000%

CB Insight's – 2021 Healthcare Digital Transformation Survey

- The COVID-19 pandemic has fundamentally changed the diagnostics landscape, as well as reinforcing the critical need for accurate and easy to use point of care and home-based diagnostics as part of a broader healthcare offering
- With a range of new OTC and home tests approved and in-market for COVID-19 testing in the US and expanded government reimbursement for home telehealth consultations driving market growth, there is a notable increase in consumer acceptance and demand for home testing. This opens a significant new vertical to market and uses for simple to use, accurate and reliable new rapid tests
- With key growth segments including the proliferation of infectious diseases and home-based testing, Atomo's best-in-class technology and versatile test solutions can help OEM and distribution partners capitalise on this sizeable market opportunity and disrupted landscape.

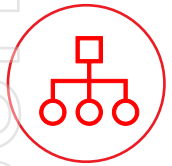
PRIORITIES FOR FY22*

Continued expansion of strategic commercialisation partnerships across key global markets, including seeking US market entry partnership

Continue to expand COVID-19 revenues with a core focus on the Australian market and expanding HIV sales in existing territories and securing commercial agreements for these products in new territories

Leverage substantial installed capacity to drive accelerated OEM partnerships/ contracts and to further commercialize Atomo devices and key proprietary components across growing POCT segments, including home testing

Development and commercialisation of new Atomo platforms for non-blood applications – focus on integrated user friendly solutions for swab and saliva rapid test applications supporting COVID and other respiratory conditions



Set up Atomo's US business and infrastructure and accelerate US commercial, sales and technical development capabilities

*The items above reflect the Company's intentions in FY22 only. They have been provided as a general guide and should not be relied upon as an indication or guarantee of future performance. There is no guarantee that these items will eventuate

atomo diagnostics

SIMPLY BETTER DIAGNOSTICS

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