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Australia

Authorised by John Kelly, Managing Director



BELL POTTER HEALTHCARE CONFERENCE

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INTRODUCTION

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 tests to the global market



Headquartered in Australia with international operations, Atomo develops, manufactures and sells innovative patented devices and rapid tests that address unmet user needs



Increasing market traction locally in Australia as well as the US, Europe and Global Health markets selling approved Atomo finished tests to healthcare distributors and Atomo devices to diagnostic partners(OEM)



Atomo has experienced strong growth since FY19, with demand for both rapid tests and home based self tests growing globally



STANDARD RAPID TEST KITS: OFF PATENT AND COMPLEX

Traditional incumbent '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%

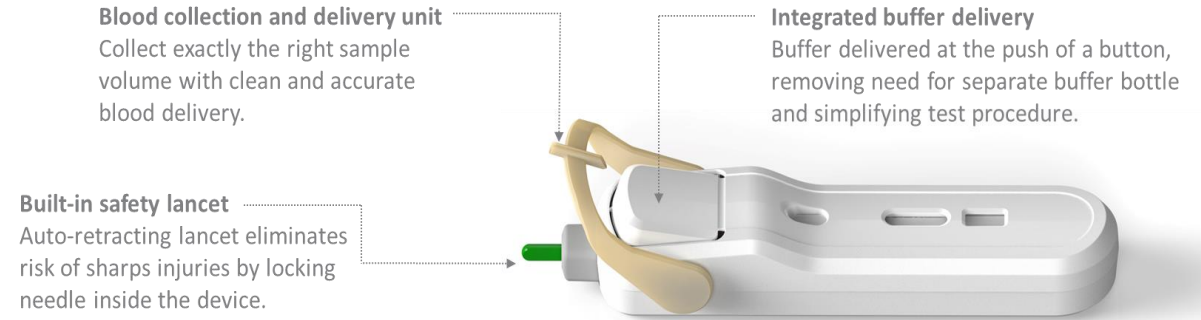
Error rates when
used by untrained
self-test users

- 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 SOLUTION – CONSUMER FOCUSED

Integrating key functionality directly into the cassette delivers significant benefits

- Usability delivers best in class user preference
- Established reliability and functionality in the field
- Removal of the need for add-on accessories
- Removing and/or simplifying steps of use
- Interlocking features to ensure correct sequencing of workflow



Pascal Test – supports professional and self test applications

Elion Self Test – a user friendly consumer focused rapid blood test device



1. Prick finger

2. Fill sample well

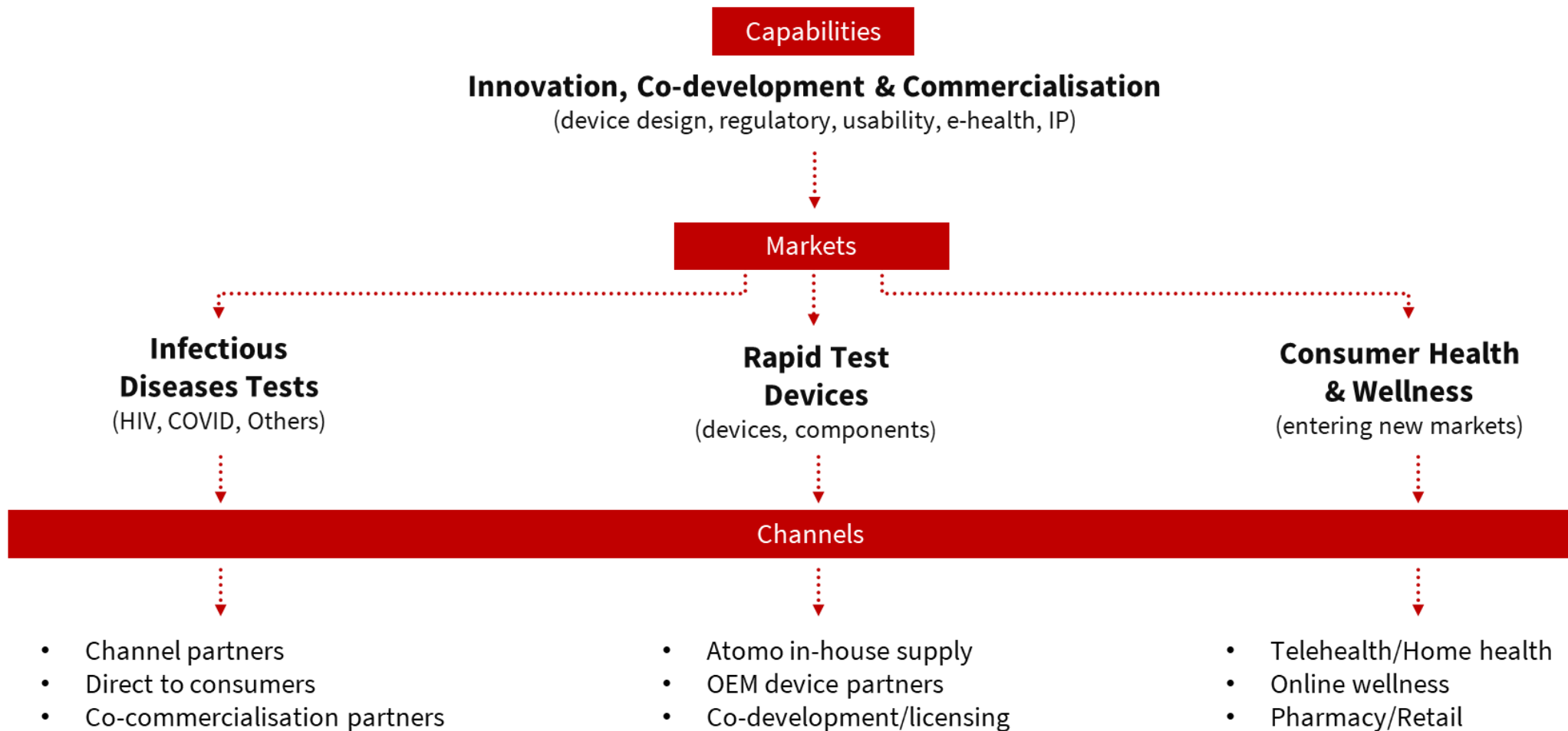
3. Press activation button

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*

ATOMO'S STRATEGIC FOCUS



UNIQUE CAPABILITIES IN POCT

The intersection between Consumer Medical Devices & Diagnostic Testing

IP Intensive

Less IP Intensive
More sales focused



Atomo DNA

Point-of-Care Self Testing

- Design and engineering
- Patent generation
- Rapid Prototyping
- Co-development
- Regulatory processes
- User centric design



Core Functionality

- Blood collection
- Saliva & swab collection
- Buffer delivery
- Interlocks
- Manufacturing machinery and processes
- IFU's
- Digital, App



Devices

- Galileo
- Pascal
- Elion
- Da Vinci
- Non-Blood devices



Finished Product

- HIV
- COVID
- Other



Customer Delivery

- Digital delivery
- Subscription models
- White label brands

Personal use only



EXISTING PRODUCTS AND CUSTOMERS

	PRODUCTS	CUSTOMERS / CHANNELS
Infectious Diseases Tests (HIV, COVID, Others)	HIV- Self Test and Professional	Iyeza, Owen Mumford (UK/EU) Mylan/Viatris (LMIC), Australia - Distributors
	COVID*- Antigen and Antibody Professional	Atomo branded Antigen tests (Australia) OEM device for Antibody tests (NG and ABI)
Rapid Test Devices (devices, components)	Blood Devices- Galileo, Pascal, Elion (pending)	NG Bio, Lumos
	Non-Blood- Swab and Saliva (commenced)	Development In process
Consumer Health & Wellness (entering new markets)	HIV- Direct to consumer Australia COVID- Emerging market in Australia	Expansion to pharmacy and removal of restrictions on advertising and promotion ST submission pending – eCommerce/ Pharmacy

* COVID-19 rapid testing detects SARS-COV-2, the virus that causes COVID-19

ATOMO'S INFECTIOUS DISEASE BUSINESS



HIV



USA:

No commercial partner in place or rights granted for POC or HIVST

EUROPE:

No commercial rights granted for POC
HIVST – distribution rights with Owen Mumford (OM)

LMIC MARKETS:

POC rights not committed
HIVST – distribution rights with Viatris

CE MARK
POC & ST

CHINA:

No commercial rights granted for POC
HIVST rights with Viatris

AUSTRALIA:

No commercial rights granted for POC or HIVST
Atomo markets its tests directly

WHO
ST PQ

TGA
POC & ST

COVID-19

COVID Antigen - Australia

Atomo has secured supply up to 20 million antigen tests during FY22 & 23.

COVID OEM Devices

With extended market life, we see some opportunity to supply custom cassettes to leading COVID antigen home tests

Neutralising Antibody

There is some prospect of neutralising antibody testing becoming a sizeable market channel



RAPID TESTING IN AUSTRALIA



- Change in public policy and regulatory positions
- Growing support for rapid testing, evidenced by changing public health position from Federal, NSW and VIC Governments and TGA regulations
- TGA has commenced process of approving at-home tests for COVID-19
- TGA has announced improved supply and advertising conditions for COVID-19 and HIV Self-Tests
- Improved ability for Atomo to communicate to market for HIV Self-Test, COVID-19 Rapid Antigen and COVID-19 Rapid Antibody tests

COVID-19 Rapid Antigen Testing

- Aged Care
- Transport and logistics
- Major retailers
- Construction Companies
- Film, TV, Opera crews
- FIFO resources companies
- Food preparation and factories
- Government tenders

HIV Self-Testing

- Direct to consumer (now open to advertising and promotion)
- Clinics and community centres
- Partnerships incl. PrEP
- Grant funded programmes and Public Health
- Pharmacies (new channel)

CO-DEVELOPMENT BUSINESS



GOAL: To become the leading provider of integrated Rapid test devices by leveraging Atomo's capabilities, IP and know-how by offering Co-Development partners access to Atomo's platforms and proprietary components

Leverage existing platforms



Accelerate roll-out of current technologies with existing approvals to existing markets (Europe, Australia) and new markets (US) with potential for partners to upgrade existing products to an Atomo platform



Elion: developed but not yet commercialised

Development beyond blood



Atomo's development & usability expertise, portfolio of patent protected technologies and proprietary know-how to enhance a Partner's portfolio of assets, products and sample types

Swab and saliva rapid test concepts in development

Custom Development



Work with partners for bespoke solutions that leverage Atomo's existing technology, that allow for cost-sharing new developments, and create locked in customer relationships through supply, licensing and royalties

Technical discussions in process



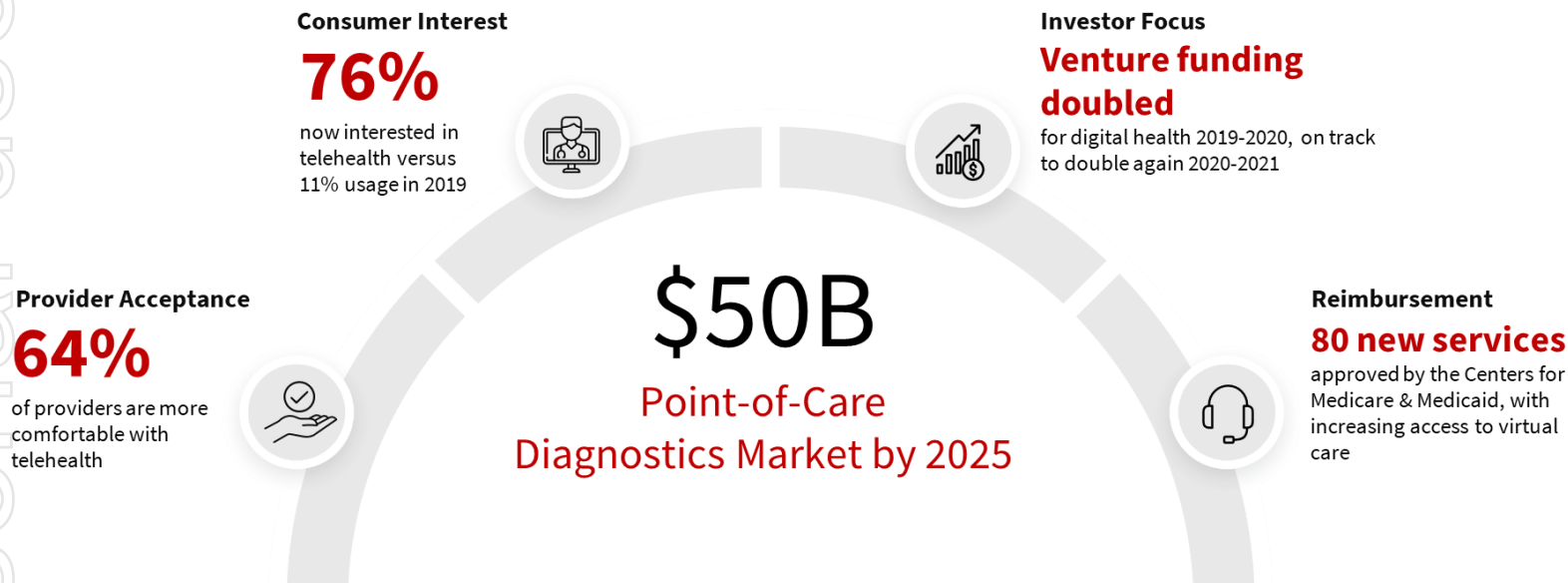
TELEHEALTH: OPENING NEW MARKETS

- COVID-19 has accelerated personalised, predictive and preventive medicine programs
- Consumer adoption and growth in Telehealth, POCT, OTC and at-home self-testing markets
- Telehealth consultations 38x higher than before the pandemic*
- Historical uncertainty from health care providers towards self-testing/at-home testing has been reduced
- Precedents have been set with regulatory authorities to approve self-testing technologies
- Usability, simplicity and accuracy are critical for diagnostics use in these settings



In the US, telehealth as a share of medical consults went from 0.2% to 13% at the peak of the COVID-19 pandemic, and has stabilised at ~6% of all consults

CB Insight's – 2021 Healthcare Digital Transformation Survey



CORPORATE PROFILE

Key financial details

ASX code	AT1
Share price (05/11/21)	\$0.25
Shares on issue	568.6m
Options on issue	23.7m
Market cap*	\$142m
Current cash (30/09/21)	\$15.2m

*Undiluted

Board Member	Position
John Keith	Non-Executive Chairman
John Kelly	Founder and Managing Director
Dr Curt LaBelle	Non-Executive Director
Connie Carnabuci	Non-Executive Director
Dr Paul Kasian	Non-Executive Director
Deborah Neff	Non-Executive Director*

Share price performance

AT1 Share Price



Major Shareholders

% (undiluted)

Dalraida Holdings Pty Ltd / John Kelly	13.1%
Global Health Investment Fund I, LLC	11.4%
Ellerston Capital Limited	7.31%
Walker Group Holdings Pty Ltd	6.70%

As per substantial shareholder notices



KEY HIGHLIGHTS - FY21

- **Atomo COVID-19 rapid tests** – Added by the TGA to the ARTG in H1 FY21 for supply in Australia. Tests launched in Q2 & Q3 FY21. Circa. 50k, primarily antibody test units sold in 2H FY21.
- **Regulatory Approval** – Atomo devices have now achieved broad regulatory approvals including FDA, CE Mark, TGA & WHO prequalification (Atomo and Customer Finished tests)
- **HIV** - Global health agreement signed between Mylan (Viatris)/Atomo and Unitaid in Q4 FY21 covering more than 135 countries. Initial orders commenced
- **OEM/Co-development business** – Ongoing technical and commercial engagement progressing with several leading multinational diagnostics companies seeking access to Atomo's rapid blood test platforms and 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
- **Financials** – Sales growth of 25%, cash receipts of ~\$8m and cash at bank of \$18m at 30/6/21



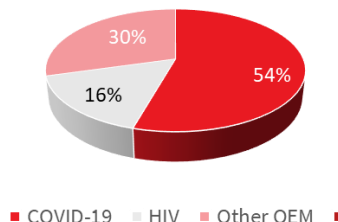
KEY FINANCIAL METRICS

FY21

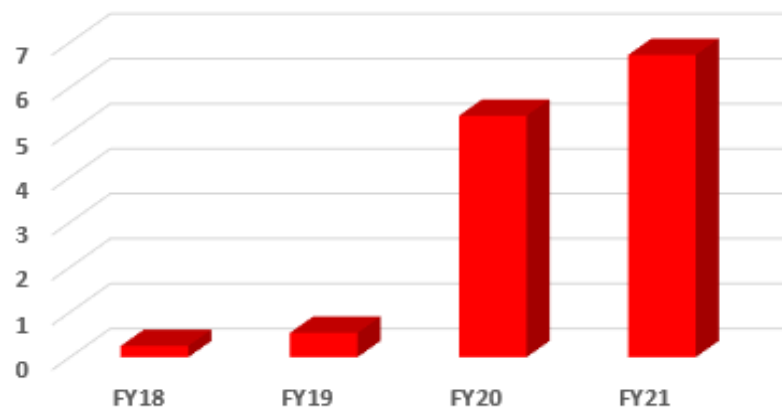
Sales \$6.72m

Gross Margin (\$m) \$3.42m

Sales Revenue Split by Product



Annual Sales Revenue (\$m)



Q1 FY22

Sales \$2.4m

Cash receipts \$2.2m

- **Cash receipts and revenues:** Cash receipts of \$2.2m from customers during the quarter, and unaudited revenue of \$2.4m
- **COVID-19 rapid antigen test sales in Australia have significantly increased since 1 July 2021**
- New arrangements with Access Bio: **US\$1.72m (A\$2.4m) cash which was received post-quarter end** and commitment to **supply up to 20m COVID-19** rapid antigen tests to Atomo
- Completed initial Viatris order for **250,000 HIV Self-Test** products to supply into the South African market as part of Unitaids agreement with subsequent orders received late in Q1 for India and two other countries
- Atomo finished the quarter debt-free and with **cash on hand** of \$15.2m

PRIORITIES FOR FY22*



Capitalising on expanding local COVID-19 opportunities, including launch of a self-test product (subject to TGA approval), and increasing resources to support growing demand across public health and private sector channels as Australia opens up to the world



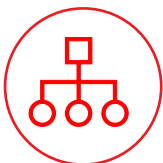
Progressing strategic partnership opportunities with large diagnostics companies looking to improve the usability and marketability of their existing point-of-care testing products, and enter the rapidly growing home-based telehealth market



Growing Atomo's HIV business through the support of key partners rolling out Atomo's HIV products globally, developing new markets and expanding Atomo's domestic sales channels given recent supportive TGA changes enabling pharmacy sales and product advertising



Ongoing development of a range of non-blood rapid test solutions, including for swab and saliva rapid testing and so significantly expand Atomo's addressable market in point-of-care testing (POCT)



Establishing Atomo's US business and upgrading the Company's commercial and business resources, capabilities and infrastructure