

Atomo Diagnostics Limited

(ASX: AT1)

atomo

Investor Update

16 April 2020

This announcement was authorised by John Kelly, Managing Director:

Atomo Diagnostics Limited
Level 2, 701-703 Parramatta Road
Leichhardt NSW 2047

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INTRODUCTION TO ATOMO

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

- Atomo's patented devices simplify testing procedures and enhance usability for professional users and untrained self-testers, compared to standard multi-component RDT kits
- Atomo's HIV self-test has regulatory approval in Australia (TGA) and the EU and UK (CE) and is prequalified by the World Health Organisation (WHO)
- More than 1.2 million Atomo rapid test devices have been sold to date, either as finished test products or as test devices sold to OEM customers
- Supply agreements in place with global healthcare distributors for rapid test products and for sale of Atomo's devices to OEM diagnostic companies for tests targeting infectious diseases including COVID-19, HIV, viral vs bacterial differentiation and for female fertility
- Contracts include an agreement with NG Biotech SAS covering France and the UK for the supply of up to 2.46 million rapid COVID-19 test devices in 2020, including to the French Ministry of Defense
- Atomo has raised A$30 million at a price of $0.20 per share in its initial public offering and listing on the ASX (April 2020), with an undiluted market capitalisation of $112 million at the IPO price





INVESTMENT HIGHLIGHTS

- Proven technology - the world's first fully integrated, blood-based rapid test devices
- Large global market - US$4.57 billion[1] lateral flow test revenues recorded globally in 2019
- Multiple revenue streams from multiple diagnostic applications and customers
- Established market position with more than 1.2 million devices sold
- Strong IP protection and scalable production with a cost-effective supply chain
- Ideally positioned to support delivery of 'best in class' rapid tests for COVID-19

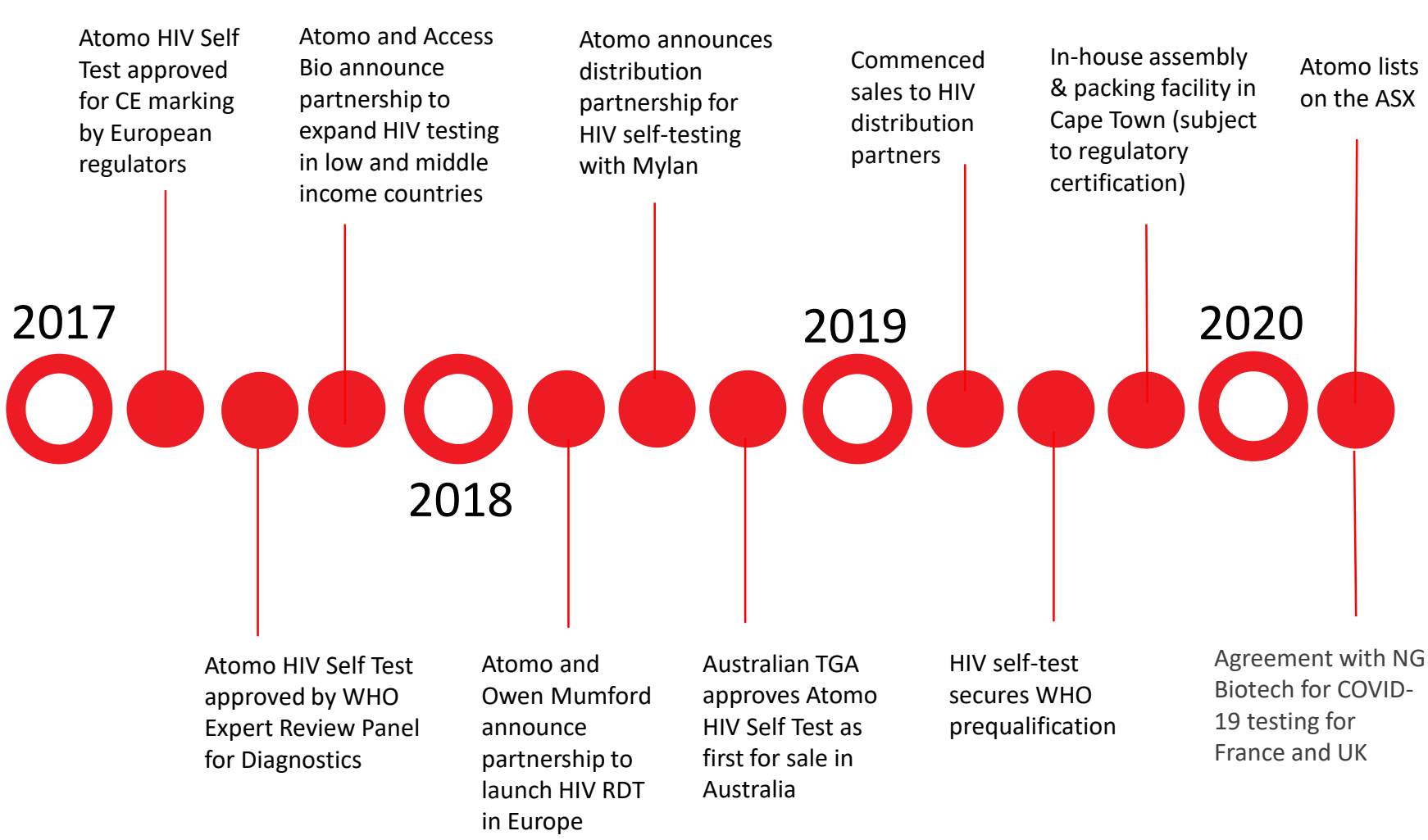
1. https://www.marketwatch.com/press-release/lateral-flow-assay-market-size-to-surpass-66-cagr-up-to-2024-2019-06-03

MILESTONES AND ACHIEVEMENTS

Early Milestones

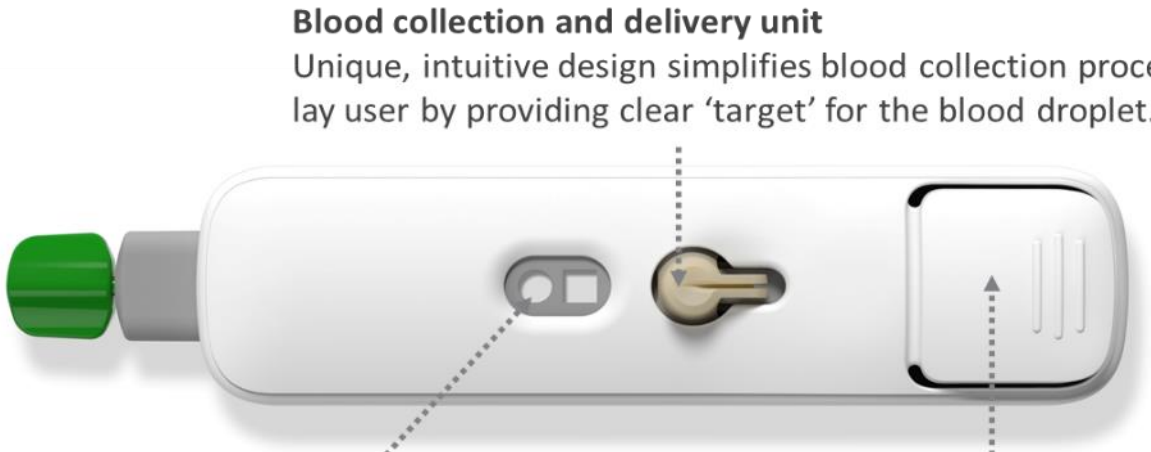
- **2014**: AtomoRapid RDT awarded 'Best in Show' at Medical Design Excellence Awards (MDEA)
- **2015**: Atomo wins 'Innovation in Export' Award at Premier's NSW Export Awards
- **2015**: US$6m loan from Global Health Investment Fund (GHIF) to support business scale-up
- **2016**: US$2.6m grant from Bill & Melinda Gates Foundation (BMGF) to develop HIV self-test
- **2016**: GHIF leads follow-on equity round investment totalling A$4.3m
- **2015 & 2016:** Atomo launches in the South African private sector to establish performance and market data

Recent Milestones



ATOMO'S PATENT PROTECTED SOLUTIONS – All-in-One Convenience

- Atomo has developed a range of unique, integrated devices for blood-based rapid diagnostic testing
- The test process can be completed in just three simple user steps, with the result provided after 15 minutes



** The Atomo Elion device shown above is developed but not yet commercialised*

ATOMO'S PATENT PROTECTED SOLUTIONS – All-in-One Convenience

Atomo Pascal:

Successfully commercialised for multiple applications, the Pascal device replaces complicated 'bits in box' chemistry set test kit formats



Lance Finger



Collect Blood



Deliver Blood



Deliver Buffer



Read Result

- The all-in-one integrated Pascal device removes the need to use multiple accessories and extensive manual handling to conveniently and reliably run a lateral flow rapid blood test
- Pascal simplifies the steps of use and controls the volume of blood and buffer delivered to the test assay; this helps reduce variability and sources of error when testing in the field

ATOMO'S BUSINESS MODEL

Atomo has two distinct but complementary business models, designed to maximise commercial opportunities and achieve scale by establishing its technologies as an innovative user friendly solution for a broad range of applications

FINISHED RDT PRODUCT



- Finished rapid test products commercialized under Atomo's own brand or private label via strategic partners
- Atomo holds product dossier and regulatory approvals

Mylan®
Owen Mumford
Iyeza Health
Your health matters to us

OEM RDT PLATFORM



- Assembled devices supplied to diagnostic manufacturers, who incorporate their own diagnostic assays (test strips).
- Customers responsible for the commercial launch and associated marketing, sales and distribution costs

RPS diagnostics
ACCESSBIO
NG biotech Next Generation

MARKET OPPORTUNITY – INDUSTRY OVERVIEW

- Clinical applications for blood-based lateral flow rapid testing include infectious disease, chronic conditions, and consumer wellness
- Global lateral flow assay market revenues were US$2.47 billion for medical testing in 2019
- Key markets for Atomo include HIV testing, COVID-19 testing, screening for viral vs bacterial infections and pregnancy testing

COVID-19 Antibody Testing (OEM)

- COVID-19 represents the biggest challenge to human health in living memory
- Testing of populations is now considered to be critical in the management of the pandemic
- Rapid antibody blood tests provide some key advantages over laboratory based molecular tests including rapid results and the ability to detect antibodies to the virus (and potentially immunity) long after symptoms have disappeared as well as asymptomatic patients.

HIV Testing (Atomo Finished Product)

- Over 183 million HIV RDTs were procured globally in 2017, excluding 150 million RDTs in China (WHO/UNITAID)
- The WHO estimates demand for HIV RDTs likely to exceed 500 million by 2021*
- In 2016 WHO recommended HIV self-testing be offered as an additional approach to complement existing HIV testing services

* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6145505/

Viral vs Bacterial Screening (OEM)

- In 2019, WHO estimated that at least 700,000[1] people died of antibiotic resistant bacterial infections
- Governments are increasing awareness with changes in policy, R&D incentives and strategies to scale up uptake of diagnostic usage
- FebriDx is the only rapid, all-in-one point-of-care test device that can identify a clinically significant acute respiratory infection (ARI) and differentiate viral from bacterial[2]

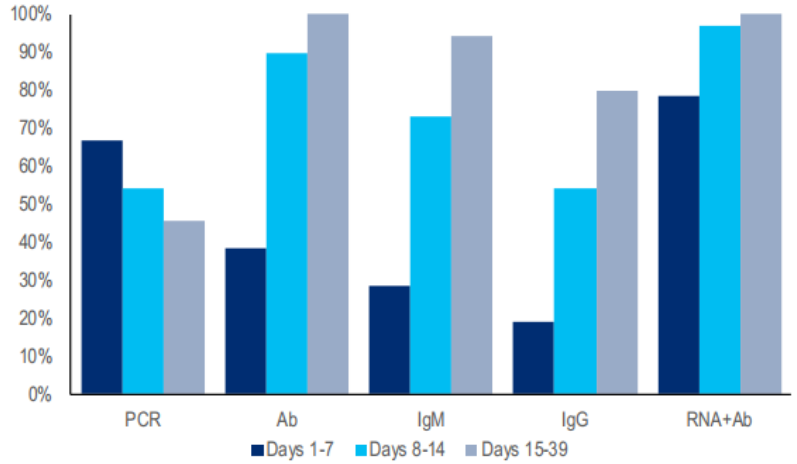
1. https://www.who.int/antimicrobial-resistance/interagency-coordination-group/IACG_final_report_EN.pdf?ua=1
2. https://www.febridx.com/the-science

COVID-19 RAPID ANTIBODY TESTING OPPORTUNITY

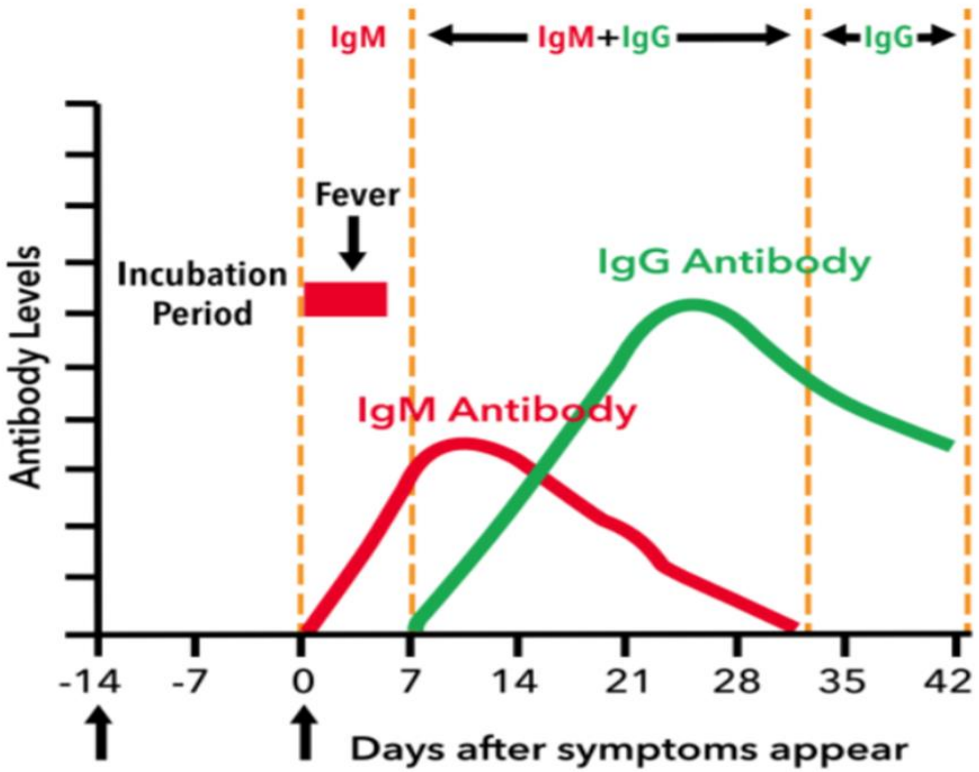
"Antibody tests are inexpensive, easily scaled and can be administered and tested at hospitals, pharmacies or as **self-testing kits within the patient's own home**, not dissimilar to currently available pregnancy assays."

Source: Citi Research April 2020

Figure 14. PCR based assays are more sensitive in detecting early disease. Serology immunoassays are more sensitive post day 8. The combination has close to 100% sensitivity.



Source: https://doi.org/10.1101/2020.03.02.20030189.



Rapid antibody tests are increasingly being used in the management of the global COVID-19 pandemic.

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ATOMO – COVID-19 TESTING

- April 2020 - Atomo entered into an agreement with NG Biotech for the supply of up to 2.46 million rapid COVID-19 test devices in 2020
- The COVID-19 tests will incorporate NG Biotech's lateral flow test strips in Atomo rapid test devices for sale in France and the UK
- NG Biotech has announced a supply contract for COVID-19 rapid tests with the French Ministry of Defense
- Atomo product has been demonstrated on French prime-time TV
- Atomo remains in discussions with NG Biotech regarding an expanded supply agreement beyond 2020
- Opportunities to supply COVID-19 tests to the Australian market are under review, subject to regulatory approval





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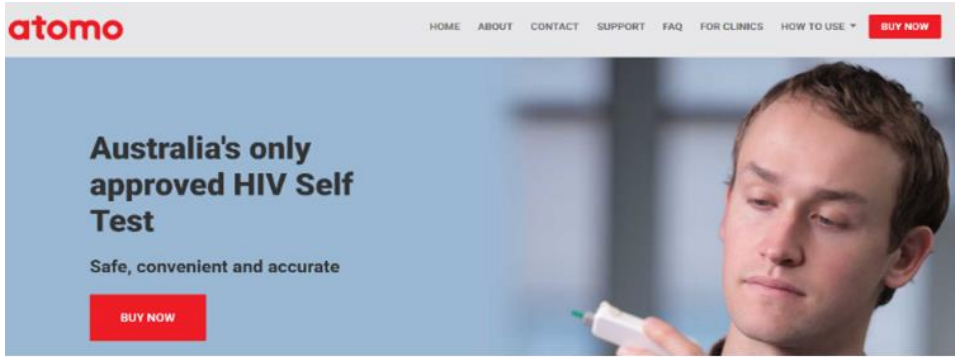
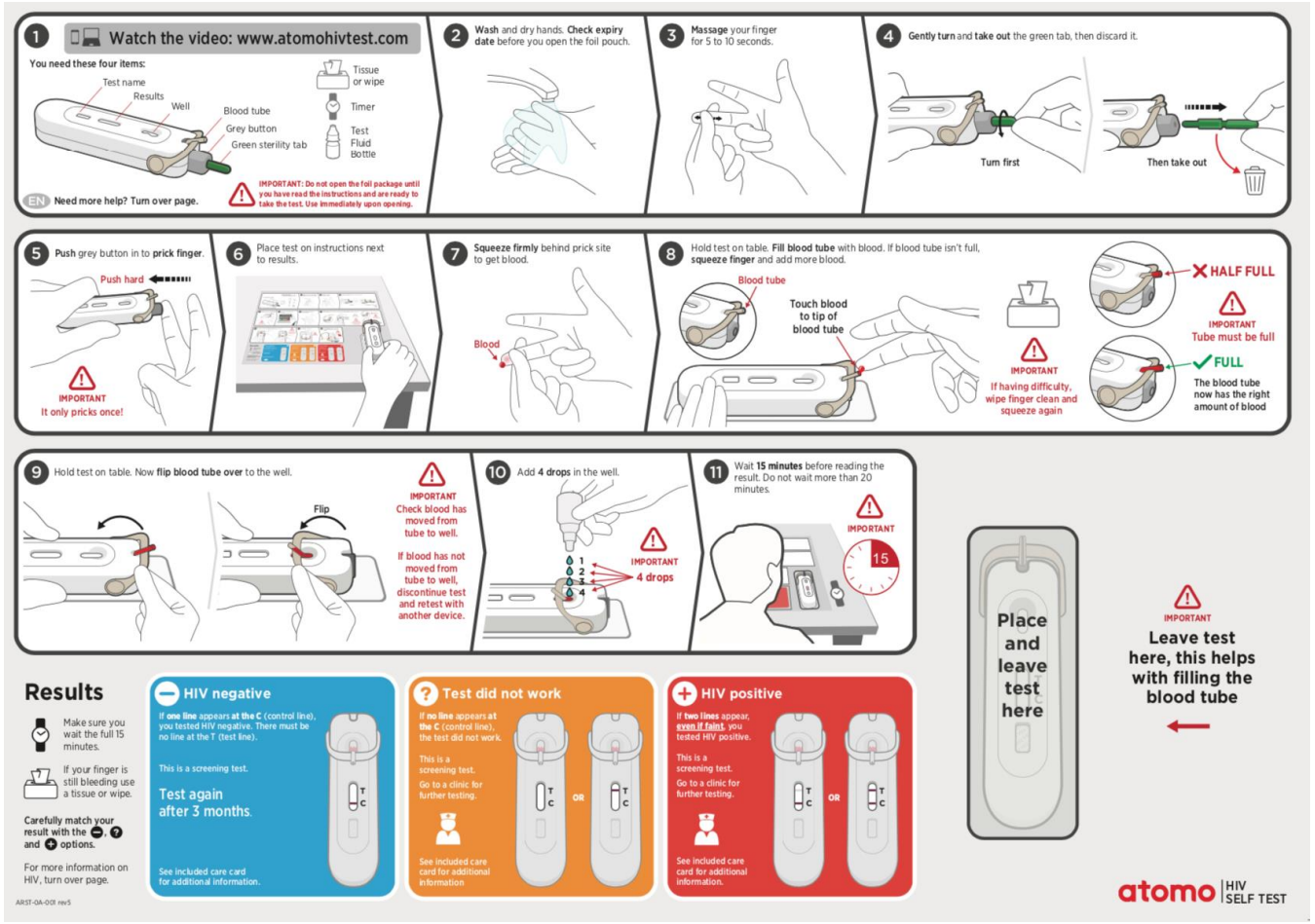
APPROVED FOR INFECTIOUS DISEASE SELF-TEST

1. Self-testing of healthcare workers and their family members living in the same household
2. Supervised testing in nursing homes and other institutions
3. Self-testing of infected essential workers that have recovered





Atomo HIV Self Test: *The only product approved in Australia to enable marginalized cohorts to self-check their HIV status in private*

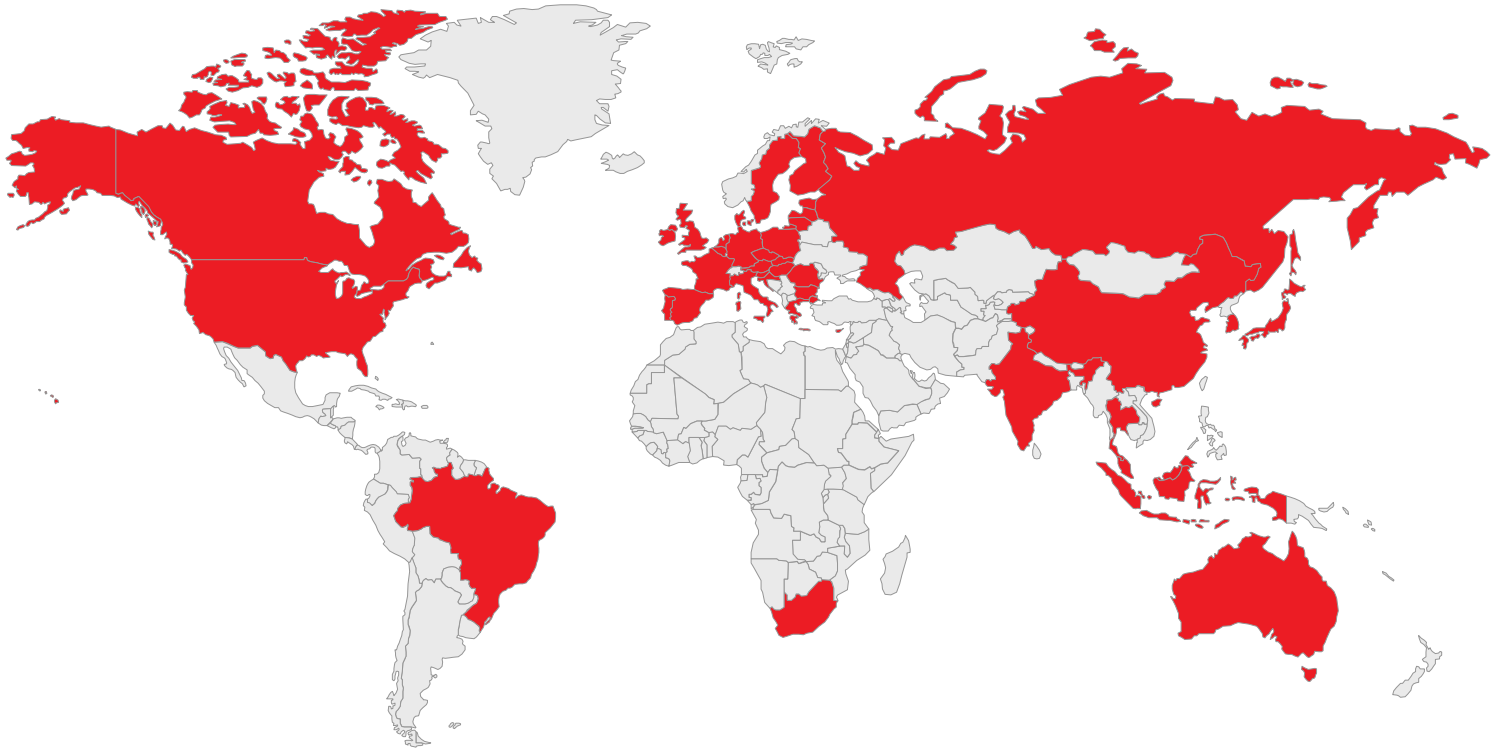
BROAD INTELLECTUAL PROPERTY PROTECTION

The patent claims are not limited to blood, lateral flow technologies, or immunoassay-based testing, meaning there is further scope to exploit and monetise Atomo's IP portfolio.

Patents cover a broad commercial and geographical scope of blood-based point of care testing

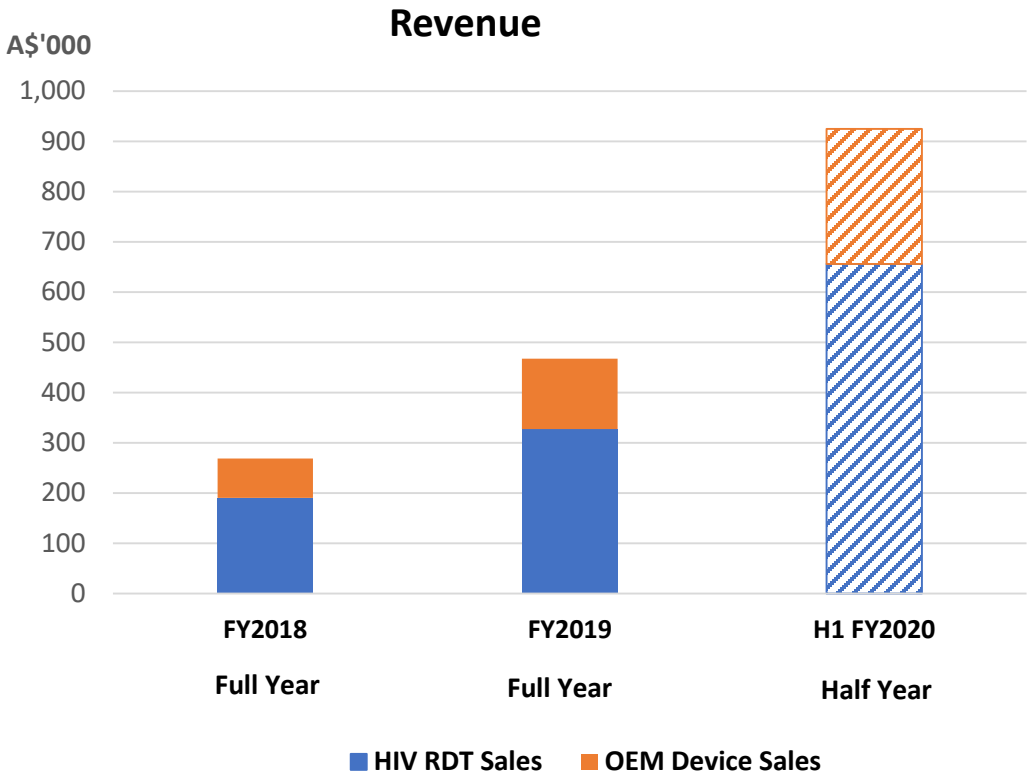
Atomo has secured comprehensive IP coverage for its technologies and manufacturing processes

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



WHO Prequalification as a prerequisite for procurement provides some protection in public health markets in a number of African countries.

KEY BUSINESS METRICS



Pro-forma (A$'000)	FY18	FY19	H1 FY20
Revenue	**287**	**540**	**937**
Cost of Sales	(228)	(443)	(544)
Gross Profit	**59**	**96**	**393**
Gross Profit Margin	20.7%	17.8%	42.0%
Other Income / (Expenses)	1,047	520	-
Employee Benefits Expenses	(1,982)	(1,770)	(1,096)
Research & Development Expense	(2,879)	(1,336)	(43)
Other Operating Expenses	(3,170)	(2,773)	(1,472)
Operating Expenses	**(8,031)**	**(5,879)**	**(2,611)**
EBITDA	**(6,924)**	**(5,262)**	**(2,217)**

- Product sales in the first half of FY20 exceeded the full year FY19, driven by:
  - the acceleration of registrations and in-country rollout of HIV products by Atomo's HIV products distribution partners
  - the launch in Europe of OEM RDT products that utilise the Pascal device
- Gross profit margin more than doubled in H1 FY20 to 42.0% driven by economies of scale and more regular production scheduling
- Atomo has accumulated tax losses of approximately $27 million

BOARD AND KEY MANAGEMENT



John Keith
Non-Executive
Chairman

Managing Director of BNP Paribas. Prior to that led management and coverage roles for Nomura Securities in Sydney and Hong Kong. Director ASIA Limited, Calliva Limited, Room to Read Australia Foundation and Ascham Foundation.
Bachelor of Arts (Hons), Master of Applied Finance from Macquarie University and a Global Executive MBA from the University of Sydney.



John Kelly
Founder &
Managing Director

Former COO Unilife Corporation, (ASX: UNI) led development of the first prefilled glass drug delivery device with auto safety retract, licensed to Sanofi Aventis for US$47m. At ResMed managed the design and commercialisation of the ground-breaking Mirage Swift mask. Mechanical Engineering (Hons) (Liverpool), Master of Manufacturing Systems Engineering, Queen's University. Belfast, Global Executive MBA (Sydney).



Dr Paul Kasian
Non-Executive
Director

Chairman of IODM Limited. Non-executive director of Eco Systems Ltd (ASX:ESL). Previously Chairman and CEO of Genetic Technologies Limited. PhD in Microbiology and MBA, both from the University of Melbourne, and GAICD. Former Chief Investment Officer and Head of Global Financials at HSBC Asset Management; Founding Director of Accordius; Founding Director of Wallara Asset Management.



Curt LaBelle
Non-Executive
Director

Managing Partner at the Global Health Investment Fund (GHIF), a social impact investment fund, which manages approximately US$108 million backed by the Gates Foundation, JP Morgan and others. Director at Alydia Health, Atticus Medical and Eyenovia. Former Managing Director at Tullis Health Investors and Vice President at Investor Growth Capital. Former chairman of Exagen Inc. (NASDAQ:XGN) and Impulse Monitoring (acquired by Nuvasive) and director of Sirion Therapeutics, SafeOp Surgical (acquired by AlphaTec) and KAI Pharmaceuticals (acquired by Amgen). B. Economics from Brigham Young University, MD and MBA degrees from Columbia University.



Connie Carnabucci
Non-Executive
Director

30 years' experience advising intellectual property and technology intensive businesses in Australia and across Asia. General Counsel of the Australian Broadcasting Corporation. Non-executive director of OFX. Connie is a former partner of Mallesons Stephen Jacques and Freshfields Bruckhaus Deringer. Member of the Business Advisory Council of the UNSW Business School. Vice President of the Cranbrook School Parents Association. She was the Chair of the NFP, Kids Giving Back, from 2015 to 2018.
B.Commerce (Marketing) UNSW, LLB, GAICD



William Souter
Chief Financial
Officer

Experienced finance executive, lawyer and investment banker. Most recently Will was Chief Financial Officer for property and construction tech company, Verton Technologies. Previously Executive Director at RFC Ambrian where for 11 years he worked closely with companies on fundraising, public markets listings and M&A. Prior to RFC, Will was a Director at PwC over a 10 year period in London and Sydney, and worked at Minter Ellison Lawyers.
GAICD, admitted to the Supreme Court of NSW. Bachelor of Laws, Bachelor of Commerce (Adelaide).

INDICATIVE CAPITAL STRUCTURE

	Shares	Options	Funds Raised	Market Cap @ 20c	Ownership (Undiluted)
Existing Securities on Issue	310.8m	31.7m	-	$62.2m	55.4%
Conversion of Convertible Notes	100.3m	-	-	$20.1m	17.9%
IPO Capital Raising (April 2020)	150.0m	-	A$30.0m	$30.0m	26.7%
Total	**561.1m**	**31.7m**	**A$30.0m**	**$112.2m**	**100.0%**

Major Shareholders	Shares	% (undiluted)
Dalraida Holdings Pty Ltd / John Kelly	73,530,248	13.1%
Global Health Investment Fund I, LLC	63,851,280	11.4%
Walker Group Holdings Pty Ltd	58,285,720	10.4%



INVESTMENT SUMMARY

- Specialist Australian Medtech device developer supplying unique and proven, all-in-one rapid diagnostic test (RDT) devices to the global market
- The technology behind the world's first fully integrated, blood-based RDTs for professional use and self-test screening is proven with more than 1.2 million test devices and OEM devices sold to date
- Distribution agreements with investment grade healthcare customers including Mylan Pharmaceutical, Owen Mumford and NG Biotech
- IP protected by extensive patents and proprietary process knowhow
- Growth accelerating with a broad range of rapid test opportunities, with the current focus on commercialising COVID-19 rapid antibody tests globally
- Independent board and quality management, led by co-founder as Managing Director
- Stakeholder recognition and support from Global Health Investment Fund, World Health Organisation, and the Bill and Melinda Gates Foundation;
- IPO has raised A$30 million to support accelerated commercialisation and scale up of manufacturing capacity

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SIMPLY BETTER DIAGNOSTICS

John Kelly
Managing Director
john.kelly@atomodiagnostics.com
+61 401 922 279

atomodiagnostics.com