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**atomo**

MARKET UPDATE

10 March 2021

ATOMO DIAGNOSTICS LIMITED | (ASX: AT1)

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# INTRODUCTION

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**Atomo Diagnostics Limited (“Atomo”) (ASX: AT1) is a medical company supplying unique, integrated rapid diagnostic test (RDT) devices to the global diagnostic market**

- Headquartered in Australia, Atomo develops and manufactures innovative patented devices that **simplify testing and reduce errors**
- **Significant proven market traction** selling approved Atomo finished products to healthcare distributors and Atomo devices to diagnostic customers (OEM) across global markets and multiple clinical applications
- **Well capitalised balance sheet** with \$24.7m cash (no debt)
- Unique ‘all in one’ rapid test devices that have the **ability to disrupt** the global point of care (POC) rapid test market



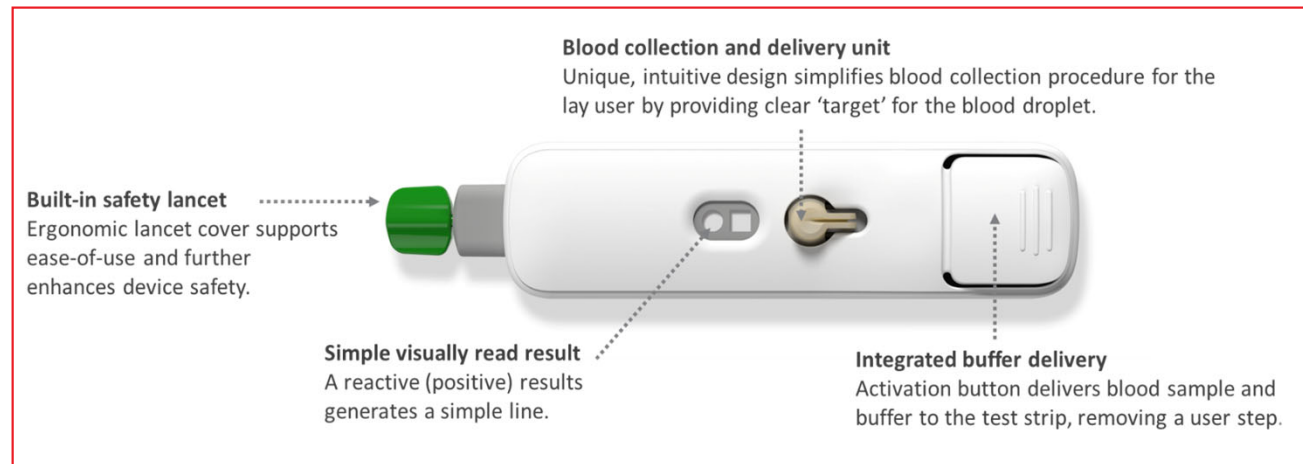
# PATENT PROTECTED UNIQUE SOLUTIONS

## Traditional 'bits in a box' kits



Standard lateral flow 'bits in a box' test kits typically contain multiple components adding complexity with user errors common and regulatory challenges for self testing

## Atomo's fully integrated user-friendly solutions\*



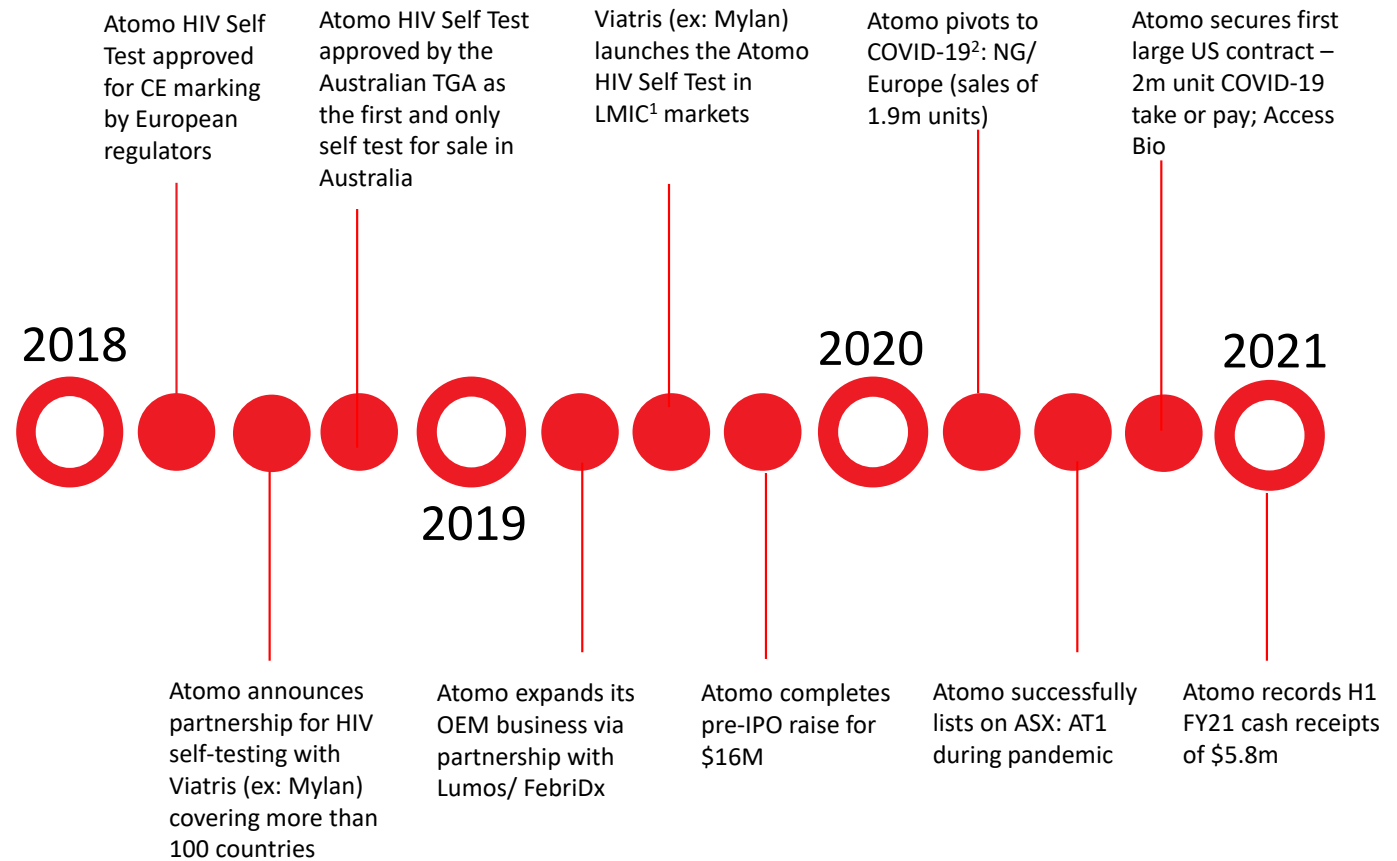
Atomo has developed a range of unique, integrated devices that deliver blood-based rapid diagnostic testing

The test process can be completed in just three simple user steps, with the result provided after 15 minutes

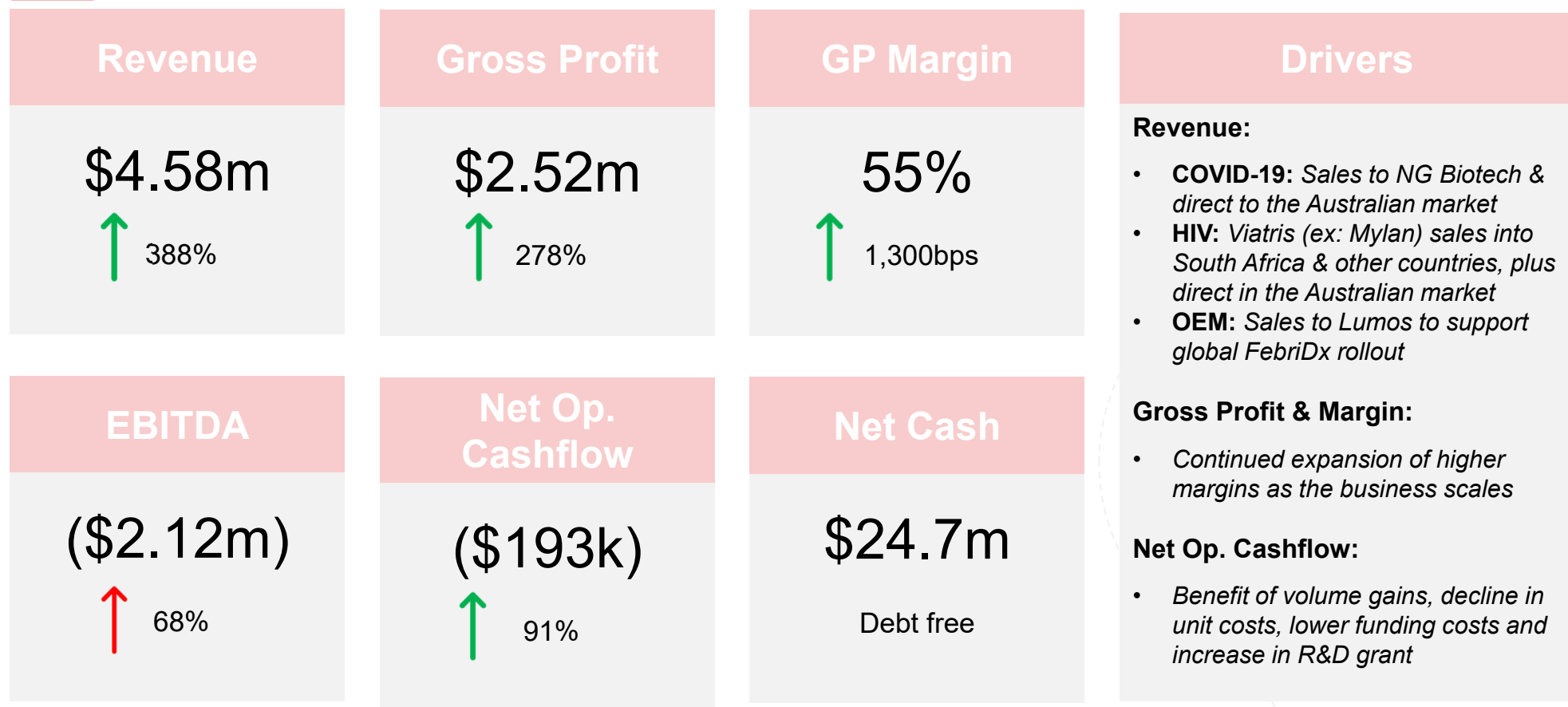
# COMPANY TIMELINE

## Pre-commercialisation

- **2010:** Founded, with initial focus on R&D and usability trials
- **2014:** AtomoRapid RDT awarded 'Best in Show' at Medical Design Excellence Awards (MDEA)
- **2015:** US\$6m investment 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
- **2017:** Atomo secures HIV Self Test approval in Europe
- **2017:** Atomo secures first HIV approval from WHO (ERP)



## KEY FINANCIAL METRICS FOR 1H FY21<sup>1</sup>- *Strong top-line growth*



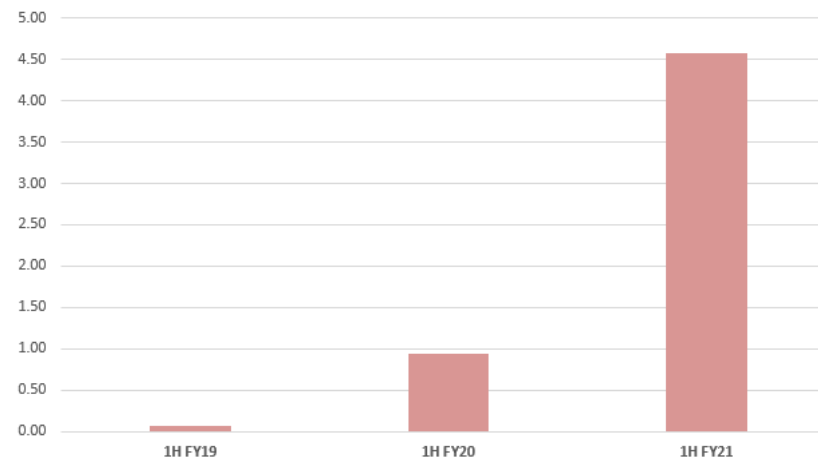
## UNDERLYING P/L & CASHFLOW – *Scale benefits materialising*

AUD	1H FY21 (\$m)	1H FY20 (\$m)	Variance (\$m)	Variance (%)
Revenue	4.58	0.94	3.64	388.5%
Costs of Sales	(2.05)	(0.54)	(1.51)	277.5%
<b>Gross Profit</b>	<b>2.52</b>	<b>0.39</b>	<b>2.13</b>	<b>542.0%</b>
Gross profit margin	55.1%	42.0%	-	-
Other Income	0.11	0.25	(0.14)	-56.2%
Employee benefits expense	(2.13)	(1.10)	(1.03)	93.9%
Foreign exchange gains / (losses)	(0.42)	0.19	(0.62)	-316.8%
Research and development expenses	(0.48)	(0.04)	(0.43)	1012.2%
Professional fees expense	(0.69)	(0.38)	(0.32)	83.9%
Other expenses	(1.04)	(0.58)	(0.46)	79.0%
<b>Underlying EBITDA</b>	<b>(2.12)</b>	<b>(1.26)</b>	<b>(0.86)</b>	<b>68.3%</b>

- Overall Gross Profit margin **increased from 42% to 55%** as new higher margin contracts delivered improved performance and scale benefits allowed the business to drive down COGS
- Overheads increased as the company and increased capability across management, technical and sales functions, plus public company expenses
- EBITDA loss of \$2.12 million as gross margins continued to improve and expenses were managed
- Strong cash conversion on sales with cash receipts totalling \$5.8m
- Net Operating Cashflow improvement to near break-even (\$193k)

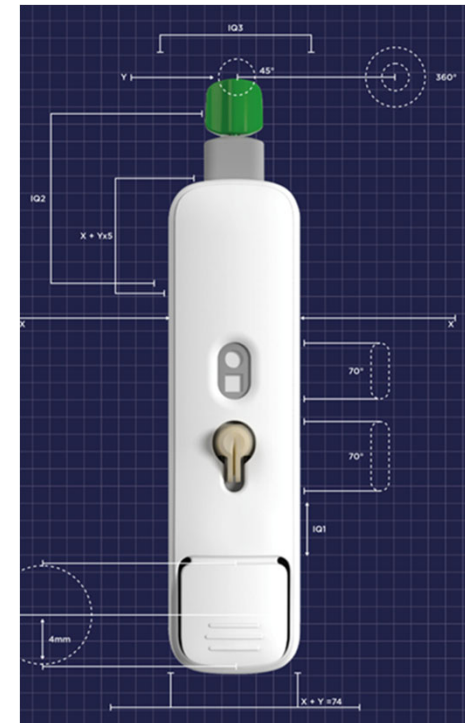
- Significant revenue growth of 389% generated by:
  - \$2.61 million from continued customer demand for COVID-19 point of care antibody testing devices, including sales of Atomo devices to NG Biotech and sales of finished products by Atomo in the Australian market
  - \$0.77 million from HIV related sales, as sales were made into South Africa, directly in Australia and in other markets via Viatrix (ex: Mylan).
  - \$1.11 million from OEM business as Lumos in particular continued to ramp up its FebriDX roll out

Half-year Sales Revenue (\$m)



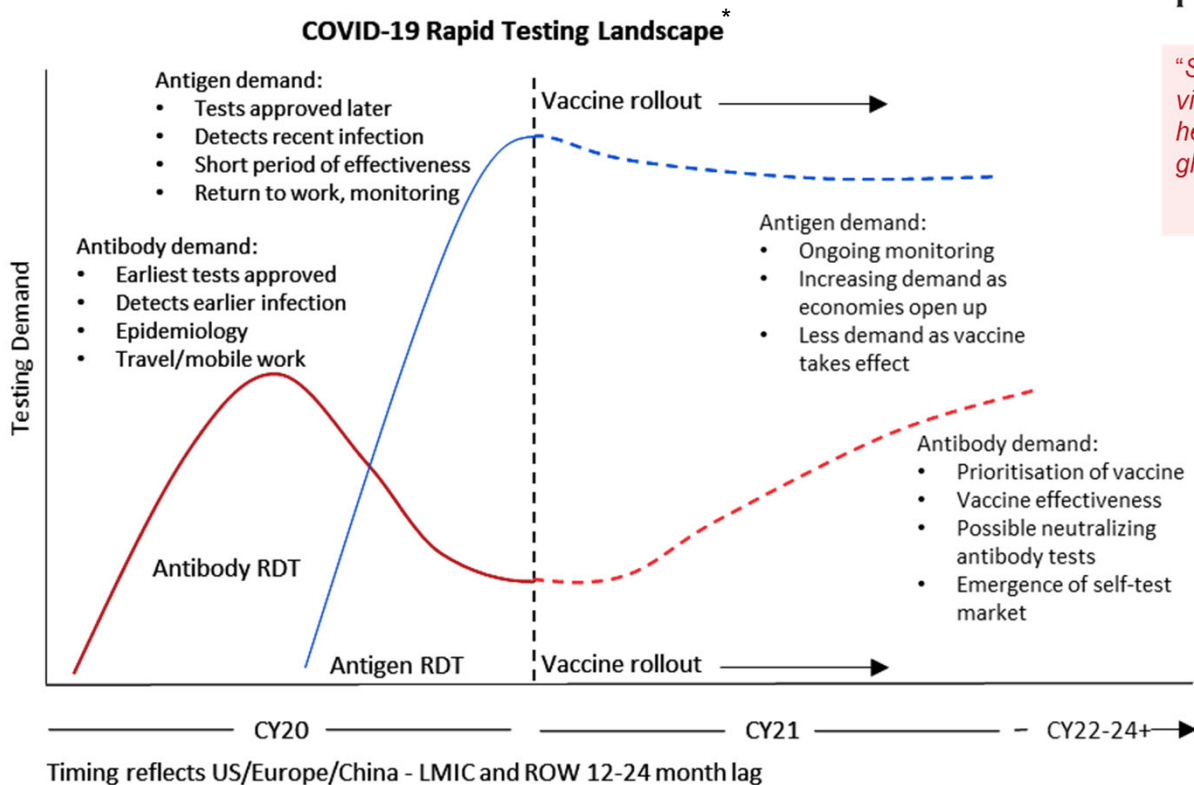
# KEY MEDIUM TERM STRATEGIC FOCUS

<h2>COVID business</h2>	<h2>HIV business</h2>	<h2>Leveraging existing platforms</h2>
<p>COVID – an ongoing test market Atomo building a global COVID test business</p>	<p>Anticipating strong growth - upgraded facility ready to support large tenders from Global Health and rollout of PrEP drugs</p>	<p>Commercialising new Atomo and OEM products:</p> <ul style="list-style-type: none"> <li>• Neutralizing COVID-19 Antibody*</li> <li>• Coeliac disease</li> <li>• Hepatitis C</li> <li>• Liver disease</li> </ul>
<h2>Expanding in-house capabilities</h2>	<h2>International expansion</h2>	<h2>Build brand awareness</h2>
<p>Investing in Atomo in-house capability for assay development and commercialisation of new finished test products</p>	<p>Atomo products to be launched in the US and establishment of a US business Pushing into new large markets</p>	<p>Increasing focus on building Atomo brand and product awareness in the global diagnostic market</p>





# COVID-19 – AN ONGOING TEST MARKET – BROAD TRENDS



## THE LANCET

Future scenarios for the COVID-19 pandemic

*“SARS-CoV-2 could continue to mutate in ways that both accelerate virus transmission and reduce vaccine effectiveness. 5–7 Vaccine hesitancy, misinformation, and disinformation could compromise the global COVID-19 response”*

David Skegg  
Department of Preventive and Social Medicine, University of Otago, Dunedin, New Zealand

## THE AUSTRALIAN

*“As scientists develop new treatments, COVID-19 will further “become an infection that we can live with”*

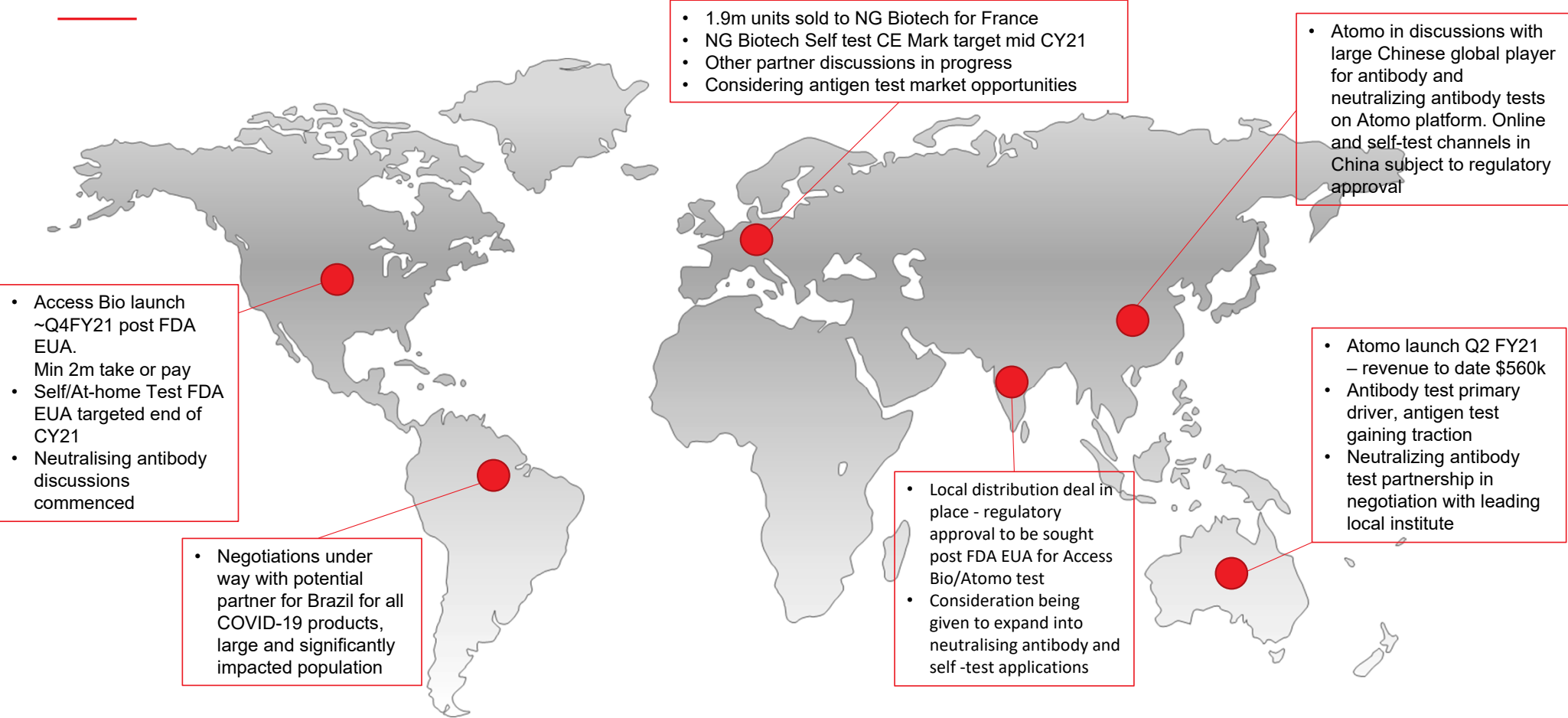
Rachel Bender Ignacio,  
infectious-disease expert at the Fred Hutchinson Cancer Research Centre in Seattle



**As vaccines raise hope, reality dawns: Covid is here to stay**

COVID-19 could shift from a pandemic disease to an endemic one, but epidemiologists say we need to accept ‘that our lives are not going to be the same’

# ATOMO'S COVID BUSINESS – EMERGING GLOBAL COVERAGE\*



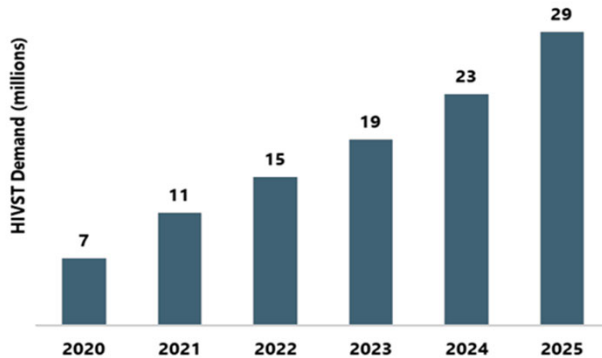
# HIV SELF-TESTING: A GLOBAL OPPORTUNITY

## Global Health Markets

### Strategic Companion Dx Partnership with Viatrix (ex: Mylan)

- Atomo has partnered with the leading global HIV drug business through an exclusive agreement covering more than 100 countries
- With WHO prequalification, the Atomo test is one of only 4 products eligible for procurement in the global health tender market

### Projected Volume of LMIC HIV \* Self-Testing Demand (millions)



## Private Sector Markets



### Focus on increasing partnerships with PrEP providers in developed markets

- Selling in Australia, UK, Germany and across LMIC markets
- Atomo is looking at options to expand its Companion Dx. business via PrEP delivery and is piloting this channel in Australia where there are currently 50,000 patients on PrEP, each of which requiring multiple HIV tests annually
- Atomo estimates the global private sector HIV Self Test market to be ~7M units in FY22

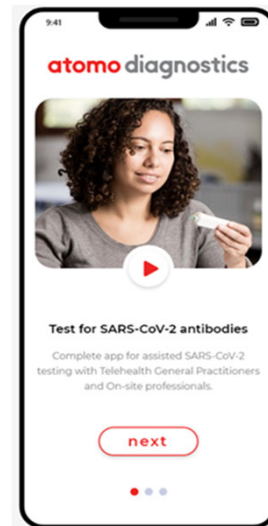
# LEVERAGING EXISTING PLATFORMS

Atomo has developed innovative integrated rapid test platforms which offer improved functionality and reliability for a broad range of clinical applications

The company is focused on commercialising a range of RDT products on its existing platforms. Products in the pipeline or under consideration include:

- Neutralising COVID Antibody, Hepatitis C, liver disease, Coeliac disease

To support the launch of new test products in the field Atomo is well advanced with the commercialisation of eHealth solutions that deliver results interpretation and traceability



The images illustrate Atomo's digital reader and app currently under development

## ATOMORAPID RDT PLATFORMS

**Galileo**



**Pascal**



**Newton**



**Fleming**



**Elion**



# GROWING ATOMO'S CAPABILITIES AND OPERATIONS

## **Atomo is expanding its development and manufacturing capabilities to expedite the commercialisation of finished products**

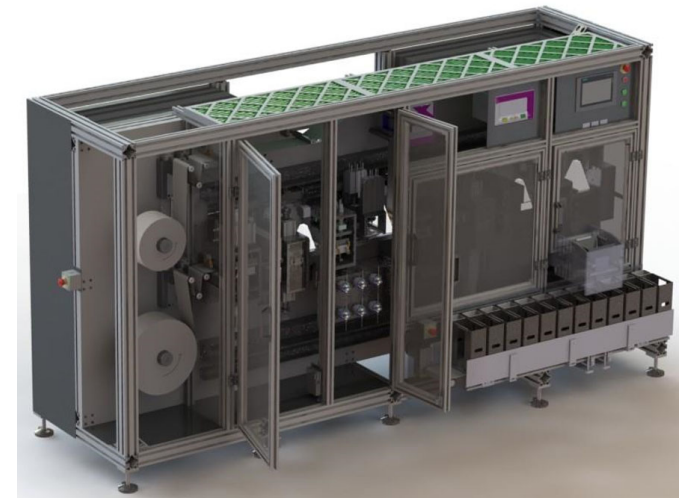
Assay development and pilot test strip manufacturing to enable Atomo to deliver key clinical applications and opportunities

## **Increased decentralised supply chain redundancy**

- North American made product for US customers and government contracts
- Continued expansion of manufacturing capacity in South Africa for HIV tenders
- Australian onshoring of development & commercialisation capabilities and offering a proven channel to market for the development of innovative Australian institute research

## ***Next gen blister manufacturing***

*Completed redesign and commenced build for additional next generation automated blister machines to support the expansion of Pascal and Elion in OEM markets, as well as providing 'best in class' platforms for new Atomo finished products*



# INTERNATIONAL EXPANSION\*

## US MARKET

Increased focus on securing additional US partners (both OEM customers and channel partners for Atomo products)

Launching Atomo based products in the US market:

- First suite of Atomo based approvals in process via the FDA EUA path for COVID-19 antibody test (Access Bio) and FebriDx via FDA 510(k) (Lumos) – CY21
- Targeting rapid tests currently being sold in the US market for OEM - CY21
- Atomo to bring own finished products to US market - CY22

## NEW MARKET ENTRY

The opportunity for Atomo's products is global with a focus on entering new large markets








- Atomo is in discussions with a large Chinese global player for products related to COVID, Hepatitis and various other products regarding possible launch in China and certain LMIC markets
- Atomo is in discussions with a Brazilian healthcare company regarding launch of Atomo COVID products into Brazil

## Europe

Continued focus on securing additional European business through the launch of COVID tests (neutralising antibody and self-test products) and the commercialisation of new Atomo tests via distributor and OEM channels

# INVESTMENT CASE

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-  **A proven innovator** – commercialised the world’s first fully integrated, blood-based rapid tests
-  **Emerging market participant** with more than 3.5m units sold globally to date and a further 2m units contracted
-  **‘Best in class’ solutions** based on Atomo’s award winning technology now increasingly recognised in market
-  **Flexible, convenient rapid test platform** that can be quickly and effectively adapted to launch new tests across a broad range of clinical applications
-  **Large & growing global rapid test market** - the global lateral testing market accounted for US\$5.4 billion in 2020\*
-  **Scalable production** with a cost-effective supply chain capacity of 1.6m total devices per month, based on a family of Robust Intellectual property and significant proprietary know-how on design and manufacturing
-  **Well capitalised balance sheet** with \$24.7m cash and no debt



**atomo diagnostics**

SIMPLY BETTER DIAGNOSTICS

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