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atomo

FY20 Results Presentation

31 August 2020

ATOMO DIAGNOSTICS LIMITED | (ASX: AT1)

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INTRODUCTION

Atomo Diagnostics Limited (ASX: AT1) is a 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 sells innovative patented devices that simplify rapid testing

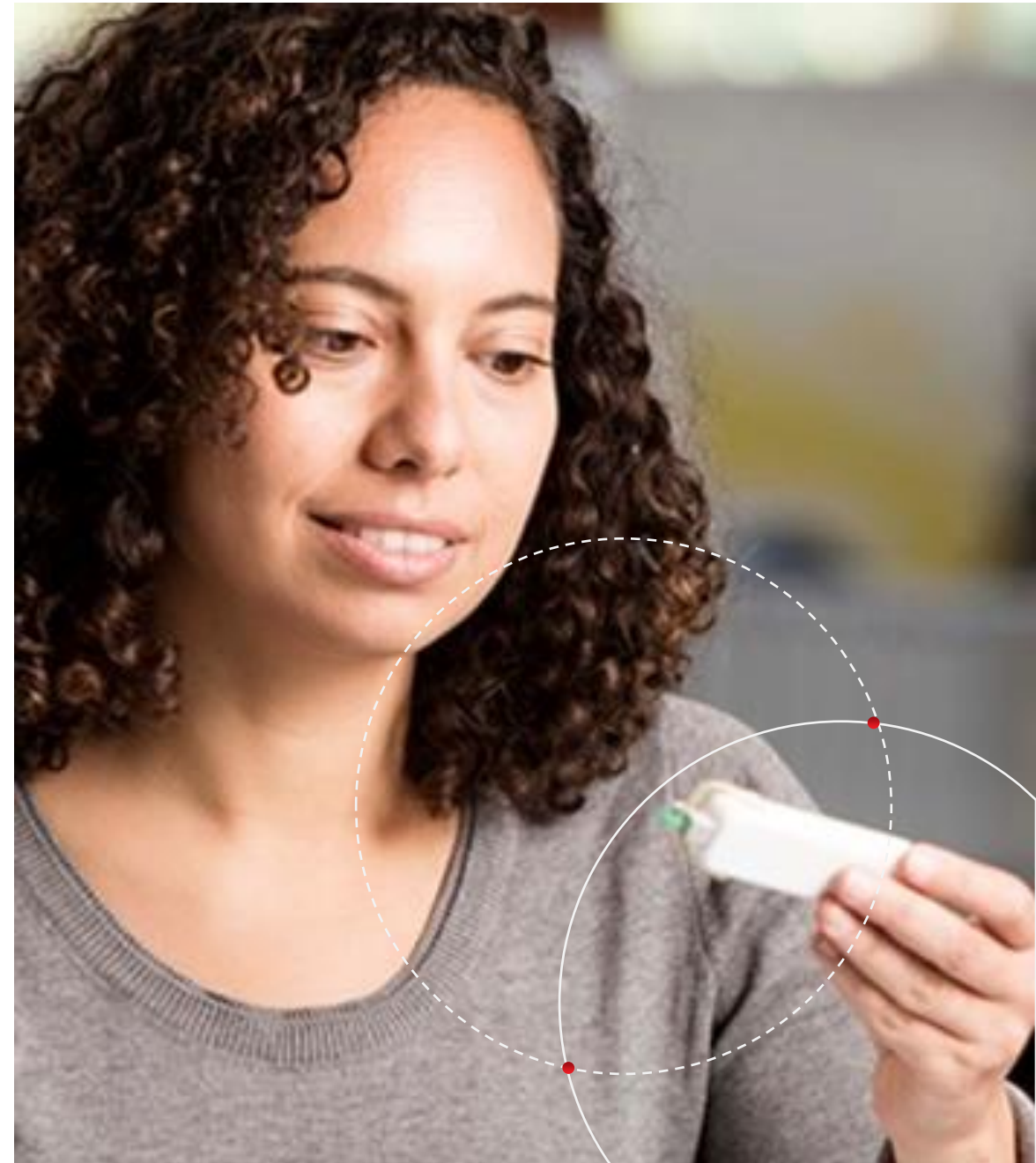


Increasing market traction in the US, Europe and other Global Health markets selling approved Atomo finished tests to healthcare distributors and Atomo devices to diagnostic customers (OEM)



Atomo has delivered a 10x increase in operating revenues of \$5.4m in FY20

Atomo listed on the ASX in April 2020, and has a current market capitalisation of approximately A\$250m



KEY HIGHLIGHTS – LAST SIX MONTHS

- Partnership agreement signed in March 20 with NG Biotech SAS (France) for COVID-19 antibody RDT devices to be distributed in France. (NG Biotech has ordered 1.75m devices to date)
- Successful IPO in April 20 raising \$30 million
- Company inclusion into ASX All Ordinaries index from June 20
- Partnership agreement signed in August 20 with Access Bio, Inc (USA) for sale of 2m (take or pay) COVID-19 antibody RDT tests in the North American market by September 21
- TGA approval granted for supply in Australia of the AtomoRapid COVID-19 antibody rapid test – August 20
- Production capacity increase from 300,000 to 750,000 total devices per month to meet anticipated demand
- FY20 sales revenue of \$5.4m; ~10x increase from FY19
- FY20 gross profit margin increases 60%; up from 18% for FY19
- Underlying EBITDA loss of \$2.4 million in FY20; down from \$4.1 million in FY19
- Cash of \$27.1 million as of 30 June 20 (no debt)



CORPORATE

KEY FINANCIAL DETAILS

ASX code	AT1
Share price (28/08/20)	\$0.445
Shares on issue	561.1m
Options on issue	31.7m
Market cap	\$250m
Current cash (30/6/20)	\$27.1m

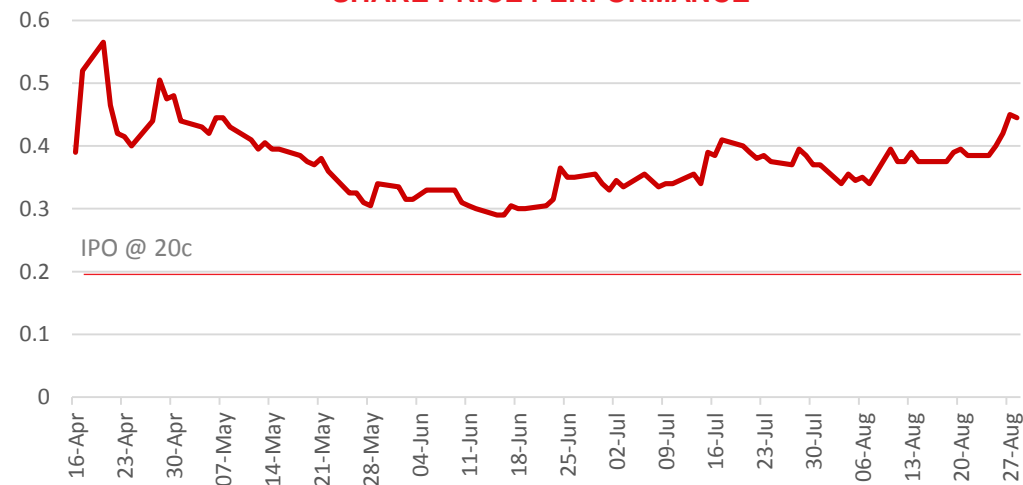
*Undiluted

MAJOR SHAREHOLDERS

% (UNDILUTED)

Dalraida Holdings Pty Ltd	13.1%
Global Health Investment Fund I, LLC	11.4%
Walker Group Holdings Pty Ltd	8.32%
Perennial Value	6.35%
Ellerston Capital	5.26%

SHARE PRICE PERFORMANCE



BOARD AND MANAGEMENT

John Keith	Non-Executive Chairman
John Kelly	Co-founder and Managing Director
Connie Carnabuci	Non-Executive Director
Dr Curt LaBelle	Non-Executive Director
Dr Paul Kasian	Non-Executive Director
Will Souter	Chief Financial Officer

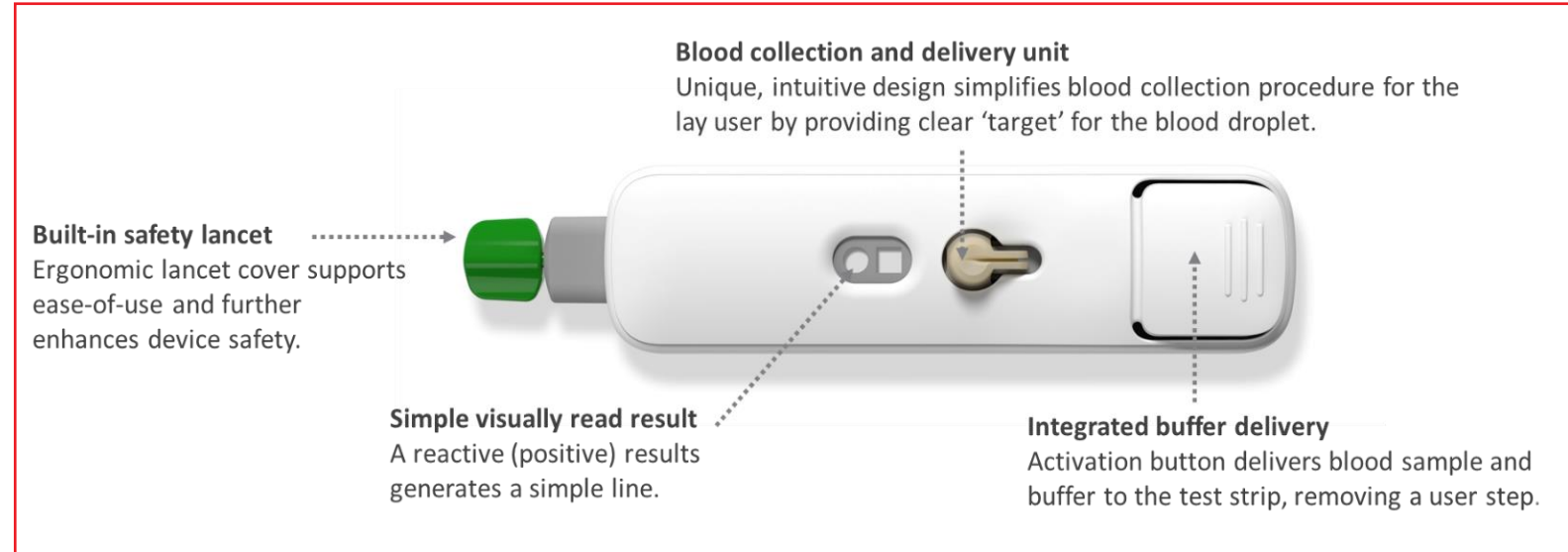
PATENT PROTECTED SOLUTIONS

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

TWO BUSINESS MODELS

Marketing strategy maximises commercial opportunities to achieve scale across a broad range of applications

FINISHED PRODUCTS



- Finished rapid test products commercialised under Atomo's own brand or private label via strategic partners
- Product dossier and regulatory approvals held by Atomo as the listed manufacturer
 - *HIV Professional Use*
 - *HIV Self Test*
 - *COVID-19 Professional Use*



OEM 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



JOURNEY TO DATE

Atomo secures impact loan & follow on equity from GHIF and a grant from the Gates Foundation

FY 16

Atomo launches its HIV Self –Test in the South African market to establish performance and market acceptance

Atomo secures CE Mark for its HIV Self-Test

FY 17

Access Bio and Atomo announce development of world's first Hepatitis C self-test

Atomo and Mylan partner for HIV Self-Test

FY 18

Atomo HIV self-test approved by Australian TGA as first and only HIV self-test

Commencement of sales to HIV distributors

FY19

Atomo (Mylan) HIV self-test prequalified by WHO

South African assembly and packing facility for HIV self-tests

FY20

Atomo lists on ASX (AT1)

Atomo secures Australian TGA approval for its COVID-19 antibody test

Atomo secures COVID-19 agreements for Europe and North America

COVID-19 ACCELERATES DEMAND FOR ATOMO TEST DEVICES

COVID-19

- AtomoRapid test devices are in high demand to help address a significant increase in rapid testing requirements globally
- Access Bio (US) – high margin, take or pay agreement for North America, 2m contracted products to be sold by Q3 CY21. Additional 2m annual extension rollover mechanism¹
- NG Biotech (France) – high margin OEM contract for France and UK, 1.75m devices ordered to date
- Commercial discussions underway for roll-out in Australia following Australian TGA approval
- Continued focus and activity of commercialisation of a COVID-19 antibody self test

COVID-19 Business Performance (FY20)

- **COVID-19 Sales Revenue - \$3.4m**
- **COVID-19 Units Sold – 1.08m**

Drivers of Growth in the COVID-19 business:

- A large and growing market forecast for COVID-19 antibody testing in 2021²
- Essential services, corporates & institutions seeking to safely manage ongoing return to work programs
- Anticipated potential roll out of large scale antibody testing in the vaccine deployment phase of the pandemic
- The need to deploy self testing if high volume community based testing is to be achieved

¹ Subject to Access Bio achieving certain performance criteria

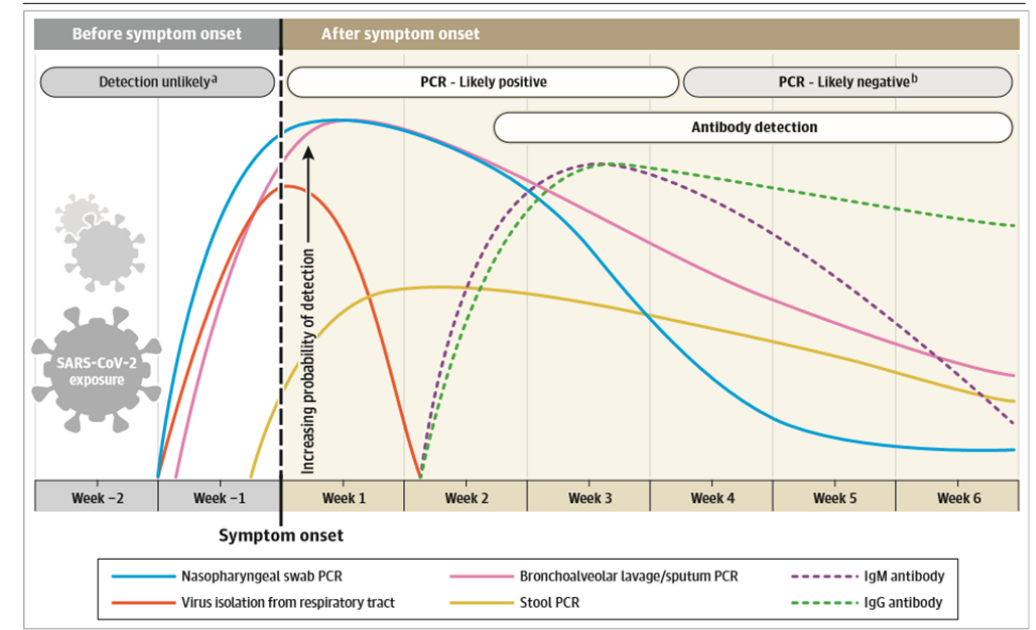
² <https://www.globenewswire.com/news-release/2020/04/30/2024901/0/en/Global-COVID-19-antibody-detection-kits-market-to-reach-5-955-million-by-2021.html>

COVID-19: ANTIBODY TESTING AND USE CASES

With TGA approval received for its professional use test, Atomo is now progressing negotiations with potential applications in several areas:

- Public health authorities – increased testing (including self-testing¹) of populations to understand exposure and transmission and advise public health policy
- Military and institutional public health channels
- Essential services
- Testing people coming out of quarantine to ensure that they are safe to re-enter the community
- Assessing fly-in, fly-out workers at mining sites and other institutional settings as well as remote healthcare deployment
- Corporate wellness and safe work programs
- Aged care and nursing facilities screening
- Future travel, tourism and vaccine delivery segments

Figure. Estimated Variation Over Time in Diagnostic Tests for Detection of SARS-CoV-2 Infection Relative to Symptom Onset



Interpreting Diagnostic Tests for SARS-CoV-2
The Journal of the American Medical Association · May 2020

“Large scale antibody surveillance studies are crucial to helping us understand how the virus has spread”¹

(UK) Health Minister Edward Argar

ATOMO TEST: ACCURACY & EASE OF USE

Public Hopital Bicêtre, France: COVID Study

- *Found that “Sensitivity and Specificity were 97.0% and 100% respectively, 15 days after the onset of symptoms.”*

Pasteur Institute, (French National Reference Laboratory): COVID Study

- *Found that 15 days after the onset of symptoms Sensitivity and Specificity were 96.8% and 100% respectively.¹*

Atomo’s Galileo Test Device:

- *Only integrated rapid blood test device approved by Australian and European regulators for both HIV and COVID-19 professional use and for self-test use for HIV*
- *Well placed for follow on self-test submissions to international regulators given the device addresses significant usability issues identified with standard ‘bits in a box’ test kits in a recent UK COVID-19 at-home study ²*



1. Pasteur Institute Report - Performance evaluation for the detection of SARS-CoV-2 antibodies, National Reference Center for Respiratory Infection Viruses (including influenza), Paris, France (Unpublished).

2. <https://www.imperial.ac.uk/news/201893/largest-study-home-coronavirus-antibody-testing/>.

HIV TEST DEVICES

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 NASDAQ listed Mylan Pharmaceutical with HIV self-tests. Agreement covering more than 100 countries
- Partnership in place with Owen Mumford for Europe. Product launched in UK and Germany in May this year
- Atomo marketing its HIV products directly in Australia via specialist health clinics and on-line channels

HIV Business Performance (FY20)

- **HIV Sales Revenue - \$1.2m**
- **HIV Units Sold - 226k**

Drivers of Growth in the HIV Business:

- Continued rollout in new countries through Atomo's healthcare partners
- Atomo approved to launch its AtomoRapid HIV Professional Use test in Australia
- Access Bio: (US) – OEM Agreement in place for the volume HIV Global Health Professional Use Tender segment



The Atomo Mylan HIV Self Test has been prequalified by the World Health Organisation and has CE Mark and Australian TGA approvals

OTHER OEM PRODUCTS

OEM Contracts

- NG Biotech: (France) – supply agreement covering pregnancy testing. Atomo tests are more accurate early-stage than urine tests and more easily deployed in Accident & Emergency settings
- Lumos/RPS: (US) – FebrIDx; screening test to distinguish between viral/bacterial infection in primary health settings - (antimicrobial resistance - AMR)
- Pipeline of clinical applications of interest indicated by our existing OEM customers

OEM Business Performance (FY20)

- **OEM Sales Revenue – \$0.8m**
- **OEM Units Sold – 266k**

Drivers of Growth in the OEM Business:

- Increasing recognition of the simplicity, reduction in error rates, and cost effectiveness of Atomo's integrated rapid test solutions
- Atomo's products ideally placed to capitalise on transition to decentralised healthcare and increased focus on POCT and consumer health
- Additional resources and product capacity post listing to support scale of the OEM business



ANTICIPATED PROGRESS DURING FY21

- ✓ COVID North American deal with US Co. Access Bio
 - ✓ AtomoRapid COVID-19 professional use test TGA Approval (Australia)
 - ✓ Total device capacity increased to 750k per month
 - AtomoRapid COVID-19 professional use test to be launched in Australia
 - AtomoRapid HIV professional use test to be launched in Australia
 - In discussion with Access Bio in relation to an initial order to support COVID-19 launch in the US
 - Scale up of business outside of COVID-19 with existing customers to be progressed
- The Atomo / Access Bio CareStart COVID-19 rapid test to be submitted to FDA of Emergency Use Authorization (EUA) as a Point of Care Test product
 - Total device capacity to be increased to 1.3m per month
 - US business and dedicated resources to be set up
 - Next Atomo Finished Product to be developed
 - The Elion Self Test Device to be launched as an OEM product for the OTC Consumer market
 - Digital eHealth solution to be implemented support OEM and Atomo product expansion

The items above reflect the Company's intentions in FY21 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.

PRIORITIES BEYOND FY21



Continued expansion of strategic commercialisation and distribution partnerships across key global markets and a clear focus on expansion of clinical test applications commercialised on Atomo devices



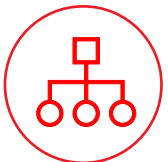
Seek new global markets for COVID-19 and HIV as well as scaling up our OEM sales channels, supporting key partners in these channels and ensuring that manufacturing capacity is in place to support significant scale up across these businesses



Launch of new Atomo finished products in high value diagnostic segments across primary care POCT and the rapidly emerging consumer health segments.



Focus on the development and commercialisation of new products and technologies including additional AtomoRapid devices, digital reader / eHealth solutions and rapid diagnostic technologies that take Atomo beyond current lateral flow segments



Expansion of Atomo's business footprint and scale to include North American business operations, increased production capacity, rollout in OEM Channels and new product commercialisation

ATOMORAPID RDT PLATFORMS

Galileo



Pascal



Newton



Fleming



Elion



Faraday



Atomo Platform range: commercialised, in development or potential future development

ADDITIONAL APPLICATIONS FOR ATOMO'S TECHNOLOGY

- Atomo intends to commercialise a number of additional AtomoRapid test products with a focus on the North American and European markets

Commercialised existing lateral flow applications compatible with Atomo devices

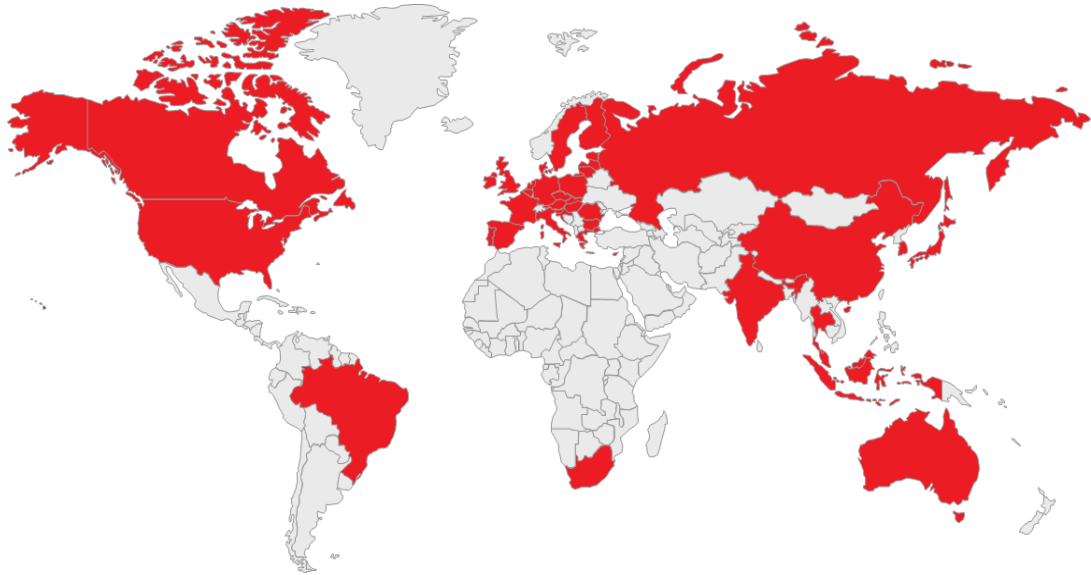
HIV, COVID-19, Hepatitis A, B & C, Syphilis, Herpes, Malaria, Dengue Fever, Mononucleosis, H Pylori, screening for bacterial infection, pregnancy & LH (ovulation), thyroid function (TSH), Allergy, Coeliac disease, Vitamin D, Liver function, Kidney function, Cancer markers: Prostate - (PSA), AFP & CEA and Cardiac markers - D-dimer (DVT), Troponin I, BNP & CK-MB

Lateral Flow POCT – A large and growing global market ¹

- Atomo is also developing digital eHealth solutions to support its products in Point-of-Care (POC) and consumer channels – areas of activity including a clip-in digital reader solution for its devices to quantify results and support eHealth capability in doctor office and in-field POCT settings, plus a consumer user app to facilitate at home deployment of tests and connectivity to telehealth services



EXTENSIVE PRODUCT AND MANUFACTURING IP & KNOW HOW



Extensive IP Portfolio:
Several patent families granted or pending (territories in red)*



Atomo's proprietary automated blister process operating: USA.

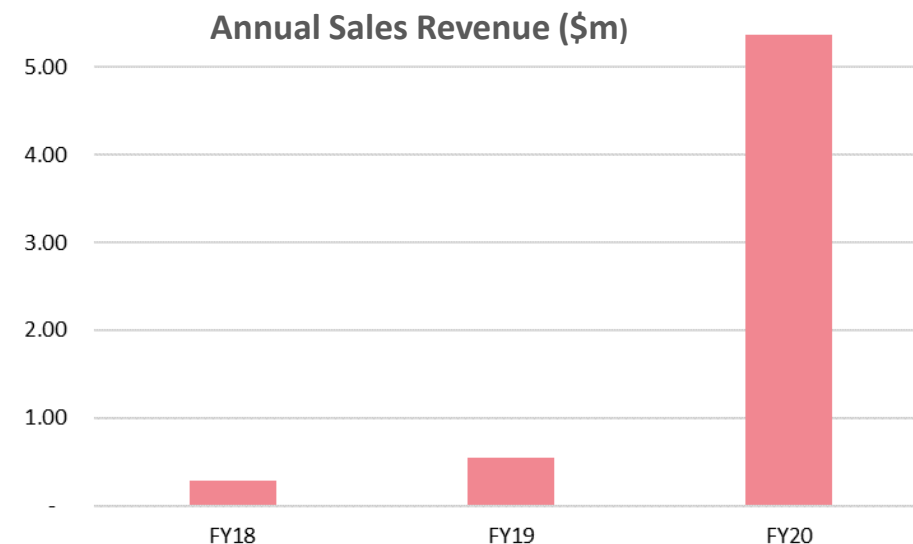


Atomo's wholly owned HIV Self Test Assembly facility in Cape Town, South Africa.

UNDERLYING PROFIT & LOSS

AUD	FY20 (\$m)	FY19 (\$m)	Variance (%)
Revenue	5.37	0.54	895%
Costs of Sales	(2.17)	(0.44)	390%
Gross Profit	3.19	0.10	3217%
Gross Margin	60%	18%	
Other Income	0.84	1.33	-36%
Employee benefits expense	(2.97)	(2.10)	41%
Foreign exchange gains / (losses)	(0.56)	(0.38)	46%
Research and development expenses	(0.70)	(1.34)	-48%
Professional fees expense	(0.93)	(0.71)	31%
Other expenses	(1.27)	(0.97)	31%
Underlying EBITDA[^]	(2.38)	(4.08)	-42%

- Gross Margin increased from 18% to 60% as the business continued to scale up and COVID-19 sales delivered higher margins
- Improvement in underlying EBITDA from a loss of \$4.08 million in FY19, to a loss of \$2.38 million in FY20.
- Total R&D spend including amounts capitalised for FY20 was approximately \$2.3m reflecting ongoing investment in product development and improvements in the manufacturing process






- Revenue increased by 895% to \$5.37 million, driven by:
 - the acceleration of registrations and in-country rollout of HIV products by the Group's HIV products distribution partners
 - the growth of Other OEM business in Europe and US
 - significant customer demand for the Group's COVID-19 point of care antibody testing devices.
- Revenue in FY20 is ~10x FY19 and ~19x FY18
- Gross Profit increased from \$0.10 million to \$3.19 million

BALANCE SHEET

AUD	FY20 (\$m)	FY19 (\$m)
Cash and cash equivalents	27.10	1.86
Trade and other receivables	3.49	0.58
Inventories	1.21	0.79
Current tax assets	1.27	0.77
Property, plant and equipment	1.45	1.15
Intangible assets	1.52	0.90
Other assets	0.06	-
Total assets	36.10	6.05
Trade and other payables	1.30	1.05
Borrowings	-	10.34
Other liabilities	0.32	0.13
Total liabilities	1.62	11.52
Net assets	34.48	(5.47)

- Cash balance of \$27.10 million as at 30 June 2020
- During the year, the Company raised \$46.05 million (before costs) in new funds including:
 - \$16.05 million via the issue of a convertible note which converted into ordinary shares at the time of the Company's IPO in April 2020; and
 - \$30.00 million via the Company's IPO in April 2020.
- Debt was fully repaid in April 2020
- Intangible assets include \$1.07 million of R&D costs capitalised during the FY20 year which was partially offset to the amount of \$0.47 million by the associated R&D Government Grant receivable in relation to that R&D expenditure.
- Continued scale up of plant and equipment Capex committed for FY21

INVESTMENT HIGHLIGHTS

-  Proven technology - the world's first fully integrated, blood-based rapid test devices
-  Market leader in fully integrated rapid tests with over 2 million devices sold globally
-  Atomo's award winning devices deliver 'best in class' rapid tests for HIV, COVID-19, and a range of other infectious disease, wellness and point-of-care test (POCT) settings
-  Large market - US\$4.57 billion lateral flow test revenues recorded globally in 2019¹ (pre COVID-19 pandemic)
-  Versatile platform can be quickly and easily pivoted for rapid testing across a range of applications (e.g. COVID-19)
-  Scalable production with a cost-effective supply chain capacity currently at 750,000 devices per month. Robust IP and significant proprietary design and process know-how
-  Pipeline of next generation RDT devices and applications to drive growth into the future

atomo diagnostics

SIMPLY BETTER DIAGNOSTICS

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APPENDIX A – Profit & Loss Reconciliation

AUD	FY20 (\$m)	FY19 (\$m)
Statutory loss for the year	(9.22)	(5.06)
Add: Depreciation and amortisation	0.69	0.56
Add: IPO expenses not taken up in equity	0.88	0.00
Less: Finance income	(0.02)	(0.02)
Add: Finance costs	5.29	0.44
Underlying EBITDA	(2.38)	(4.08)

- The underlying EBITDA of -\$2.38m presented reconciles to the statutory loss for the year of \$9.22 million by removing the impact of IPO costs, depreciation and amortisation and financing costs which were predominantly non-cash accounting expenses described further below
- IPO expenses represented one-off costs associated with the IPO which were recognised in profit and loss and not taken up in equity
- Finance costs of \$5.29 million incurred during FY20 comprised the following:
 - cash finance costs of \$2.04 million comprising:
 - \$0.45 million plus \$0.76 million (totalling \$1.21 million) relating to actual cash interest payable on the GHIF loan and converting note
 - \$0.83 million in costs associated with the raising of the converting note
 - non-cash finance costs of \$3.25 million comprising:
 - effective interest rate adjustments relating to the converting note and GHIF loan (\$7.06 million)
 - fair value adjustments totalling \$3.80 million (income) in relation to the warrants attached to the GHIF loan, and the embedded derivative on the converting note