Atomo Diagnostics Limited Level 1, 3-5 George Street Leichhardt NSW 2040 Australia



### FY22 RESULTS

25 AUGUST 2022

ATOMO DIAGNOSTICS LIMITED | (ASX: AT1)

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# **KEY VALUE DRIVERS**



A visionary diagnostics company reimaging consumer focused testing and delivering best in class usability in the growing point of care and decentralised test market



Strong financial position, committed investors, an experienced board & management team and a motivated cohort of professionals across the business



Proven innovators – award winning products, robust patents and proprietary knowhow successfully applied to address rapidly growing user needs in the market



Validated attractive solutions for OEM customers and for enabling Atomo finished products addressing high value applications



Capital spend essentially complete with core product technologies developed and capacity to manufacture that technology at scale now fully installed



Broad acceptance of rapid testing and strong growth evident in decentralised and home-based testing segments, where meeting user expectations of convenience and simplicity is critical



# COMPANY SUMMARY

Atomo Diagnostics Limited (ASX: AT1) is an innovative medical device diagnostics company supplying unique, integrated user friendly rapid diagnostic test (RDT) devices and finished point-of-care rapid tests to global partners



Headquartered in Australia and listed on the ASX, Atomo develops, manufactures and sells innovative rapid tests and test devices that address unmet user needs in point of care testing, at home and in the field, via its international operational and commercial networks

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Increasing market opportunity globally supplying approved Atomo finished tests to healthcare distributors and Atomo assembled devices to diagnostic test partners (OEM). Atomo solutions now increasingly recognised as delivering best-in-class usability and accuracy in point of care settings



Atomo has since FY19 experienced YoY growth, with cash receipts from customers for FY22 of A\$16.3 million (US\$11.5m)

Cash on hand: A\$12.9 million (US\$9m), at 30 June FY22



## FY22 KEY ACHIEVEMENTS AND CHALLENGES

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Completion of industralisation of operations to support volume production of Atomo products, including blister manufacturing – up to 18 million per annum of installed cassette capacity now available



Successful participation in the local COVID-19\* market with more than \$10m in sales revenue for the year, and well positioned for further market demand in FY23 and beyond



Set up of Atomo's US business, scale up of commercial activities including senior resources, representation at key conferences and increased promotion of Atomo's unique solutions in the market



Development of an Atomo integrated swab device to increase the addressable market being targeted by the company. Encouraging preliminary internal evaluation results and good market interest for the solution upon debut at AACC\*\*conference



Appropriate use of funds to ensure a strong balance sheet at year end and available capital to support FY23 activities, including completion of the swab device development and development and commercialisation of the next Atomo finished test product

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

\*\* American Association for Clinical Chemistry

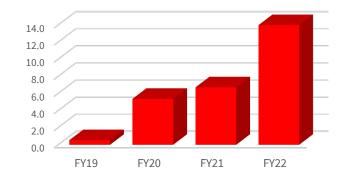
# FY22 FINANCIAL RESULTS

# FY22 - PROFIT & LOSS

AUD	FY22(\$m)	FY21(\$m)	(%)
Revenue	12.34	6.72	84%
Cost of sales	(8.09)	(3.30)	(145%)
Gross Profit	4.25	3.42	24%
Gross Margin	34%	<b>51</b> %	
Licence and settlement fee income	1.65	-	100%
Total revenue	13.99	6.72	108%
Gross Margin (inc lic & fees)	42%	51%	
Other income	1.03	0.81	27%
Employee benefits expense	(4.10)	(3.81)	(8%)
Foreign exchanges gains/(losses)	0.09	(0.41)	122%
Research and development costs	(1.41)	(0.82)	(72%)
Professional fees expense	(2.33)	(1.79)	(30%)
Other expenses	(2.88)	(2.19)	(32%)
Underlying EBITDA	(3.70)	(4.79)	23%

- Strong revenue growth in FY22
- Total GM of 42%, lower than FY21 due to skew to COVID Antigen product resales, and HIV LMIC global pricing
- OpEx steady (<A\$1m per month)</li>
- Underlying EBITDA 23% improvement on FY21

Annual Sales Revenue (\$m)



- Total customer revenue increased by **108% to \$14m** continuing strong year on year growth since commercialisation
- FY22 Total Income (incl R&D rebate) of \$15m comprises:
  - \$10.4m from the sale of >1m COVID-19 rapid tests
  - \$1.8m from the sale of >500k HIV rapid self-tests
  - \$1.65m in licence and settlement fees from Access Bio
  - \$120k in other customer revenue
  - A further \$1.0m R&D rebate income

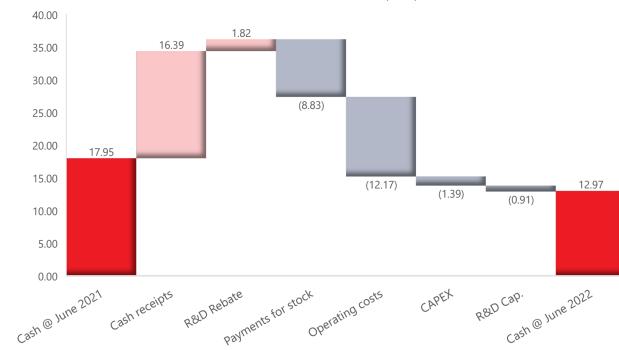
# FY22 - BALANCE SHEET

AUD	FY22 (\$m)	FY21 (\$m)
Cash and cash equivalents	12.97	17.95
Trade and other receivables	2.68	4.49
Inventories	3.42	3.04
Property, plant and equipment	3.67	3.69
Intangible assets	3.57	3.00
Other assets	0.32	0.07
Total assets	26.63	32.24
Trade and other payables	1.08	1.78
Other liabilities	0.74	0.37
Total liabilities	1.82	2.15
Net Assets	24.81	30.09

- Cash balance of \$12.97m at 30 June 22 and debt free
- COVID-19 stock on hand at year end continuing to be sold over FY23
- Continued investment in manufacturing and production capacity such that Atomo is now in a position to produce both Galileo and Pascal devices at scale, with the second generation blister machine completed
- Ongoing investment in R&D to continue innovation in rapid test devices for other sample types, in particular swab testing, with ~\$2.1m in spending during FY22\*

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# FY22 - CASH FLOW



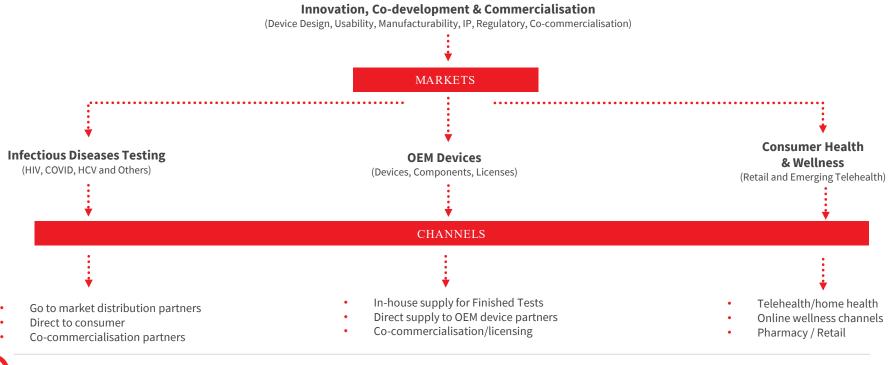
FY22 Cashflow activities (\$'m)

- Cash receipts of \$16.39m from customers as strong COVID sales, together with growing HIV business and the settlement and licence fees from Access Bio, drove cash inflows
- Cash payments for stock of \$8.83m related primarily to purchase of COVID-19 rapid tests, a number of which remain on the balance sheet for sale in FY23
- Opex, capex and R&D activities in line with expectations
- Year end balance of \$12.97m provides good runway and platform for continued operations

# BUSINESS SUMMARY

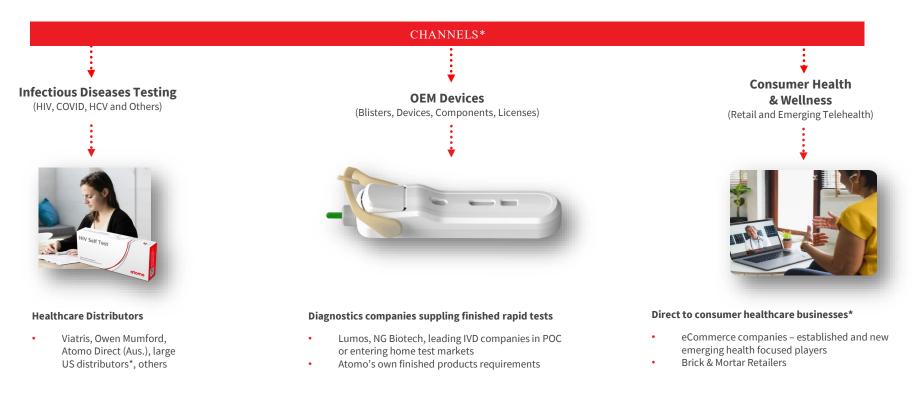
# ATOMO'S STRATEGIC FOCUS

#### CORE CAPABILITIES



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# **PRODUCT CHANNELS**

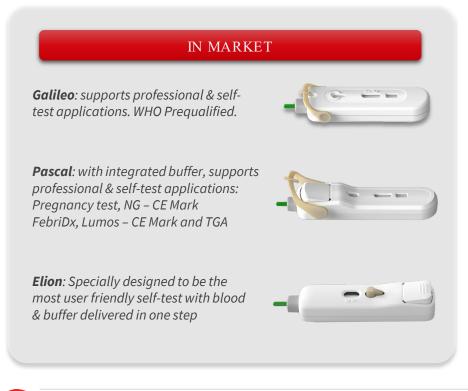


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# UNIQUE TECHNOLOGY & KNOWHOW

# ATOMO'S BLOOD TESTING SOLUTIONS



# 

ST User App

Video and animation of user steps – multiple languages

Image Recognition to interpret results (less user error)

Qualitative and Semi-Quantitative results

Atomo's patented Blood delivery QC algorithm

\* Fully developed and ready for commercialisation

#### Desktop Reader\*



Bespoke platform designed for small desktop reader

Integrated buffer and blood delivery (based o Pascal)

Fully quantitative results

Network compatible

Back-end software already validated and commercialised

\*\* Proof of concept developed – not fully developed for commercialisation

# ATOMO SWAB PLATFORM

The Atomo Swab Platform is a unique (patent pending\*) device developed using Atomo's existing core IP and knowhow.

Developed to improve usability and performance of swab-based rapid tests, this product expands Atomo's product range beyond blood-based testing.



Designed to support swab testing across and multiple applications (Nasal, nasopharyngeal, throat, STI and other types of swabs).



The swab sample and the buffer solution are mixed efficiently in the chamber and the device delivers all of the pre-sample to the test cassette. This increases the sample concentration and more volume precision delivered to the assay.



The device has integrated Atomo's patented blister technology. The device automatically delivers a controlled volume of premixed sample to the test strip, which allows for better usability and volume precision when compared to standard multi-component kits.

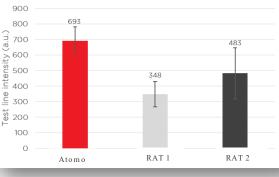


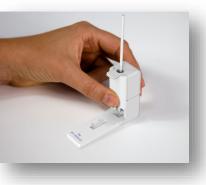
Is compatible with existing rapid test cassettes. This means manufacturers do not need to modify existing assays or products on the market.



\*Patent application number: 2022900285/P1812AU00

APMU vs Standard RAT Test Line Intensity





The Atomo Swab Platform delivers a measurable line intensity improvement when compared directly to two standard kits format swab rapid test products \*\*

\*\* Based on internal company testing, not verified as yet by independent external studies

## **OPERATIONAL CAPABILITY & EXPERTISE**

Atomo has used proceeds from the IPO to expand its manufacturing capabilities to enable the company to commercialise a larger range of finished home tests, and to deliver improved economics for supply

The company has invested in an improved manufacturing process for automated high volume blister components. Compatible with Pascal & Elion based blood tests and the Swab Test Device, this proprietary integrated reagent functionality offers best in class usability across a range of point-of-care test workflows

#### Increased decentralised supply chain capability and expanded capacity

- Goal of establishing North American made product capability for US customers and Government contracts (blister manufacturing currently in US and moulding operations under development)
- Validated annual cassette capacity is currently ~18 million cassettes
- Atomo runs an integrated SAP ERP system for all global operations and logistics

Atomo's Gen II Blister machine currently being qualified in Sydney



- Patented and commercialised proprietary reagent blister component / delivery process
- Supports integrated test devices that require a controlled reagent volume to run an assay
- Atomo has developed an automated manufacturing process to produce in volume with a second machine built and in validation

## **REGULATORY APPROVALS**



#### CE MARK (Notified Body BSI): PASCAL and GALILEO – both approved for Professional Use and Self Test

SymplitudebyMe HIV Self Test (Atomo), AtomoRapid HIV Prof. Use (Atomo), Pregnancy hCG Prof use (NG Bio), Pregnancy hCG Self-Test (NG Bio), FebriDx AMR screen Prof. Use (Lumos), COVID-19 Antibody Test (NG Bio) Self-Test



#### GALILEO approved for Professional Use and Self Test,

Atomo HIV Self Test (Atomo), AtomoRapid HIV Prof. Use(Atomo), COVID-19 antibody test Prof. Use (Atomo ) **PASCAL for Professional Use** FebriDx AMR screen Prof. Use (Lumos)



### GALILEO approved for Self Test

Mylan HIV Self Test (Atomo)



GALILEO approved for Prof. Use CLIA waived (EUA) - CareStart COVID Antibody Prof. Use (Accessbio) PASCAL 510(k) Prof. Use - in process for FebriDx AMR (Lumos)



**Notified Body BSI** : Atomo's quality management system is robust. Over the last three regulatory audits conducted by regulators on the company's QMS there has not been a single nonconformance issued

(Listed Manufacturer)

## A LEADING HIV RAPID TEST

Atomo has developed and successfully launched the world's first integrated, blood-based RDT solutions for professional use and self-test HIV screening:

- With regulatory approvals including CE Mark for Europe, Australian TGA, and prequalification by the World Health Organisation, the company's HIV business is growing
- Finished product assembly is carried out at the company's certified facility in South Africa and the product is distributed by Viatris (Mylan) in LMIC markets
- Atomo is now focused on further expansion of its HIV business and is aiming to find partners to support launch in additional market and to expand professional use sales



The Atomo HIV Self Test is the first and only HIV self-test to have been approved by the Australian Therapeutic Goods Administration (TGA).



Mylan (Viatris) HIV Self Test (manufactured by Atomo) - one of two products included in the recent Unitaid HIV Global Access Tender



Atomo has successfully launched its Self Test HIV tests in Europe and Australia

### OTHER FINISHED TESTS

Atomo has partnered with NG Biotech and Lumos Diagnostics to provide the cassettes used to produce the Blood Precision hCG Pregnancy Test and FebriDx Antimicrobial Resistance (AMR) screening tests

- The Blood Precision hCG pregnancy test offers results in 5 minutes and is sold in both professional use and self-test channels. The blood-based format is more secure and reliable than urine and saves up to 85 minutes\* in potential Emergency Room time
- FebriDx identifies and differentiates viral from bacterial acute respiratory infection.
  With 99% accuracy, this test has been shown to reduce unnecessary antibiotic prescriptions by up to 80%\*\*
- These products have secured regulatory approvals in a number of markets, including Australia, Europe and Canada

\*Caroline Legoupil, Isabelle Enderle, Flore-Anne Le Baccon, Claude Bendavid, Lucas Peltier, Estelle Bauville, Jean Leveque, Vincent Lavoue and Maela le Lous Performance of a quick pregnancy test on whole blood in early pregnancy units September 2017 \*\*Davidson M. FebriDx point-of-care testing to guide antibiotic therapy for acute respiratory tract infection in UK primary care: A retrospective outcome analysis. J Infect Dis Preve Med. 2017;5:165.

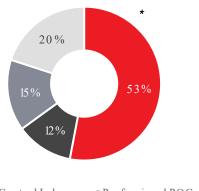




# GROWTH STRATEGY

### DIAGNOSTIC LANDSCAPE AND TRENDS POINT OF CARE PROLIFERATION

### COVID 19 has transformed the diagnostic testing landscape



### Central Lab Professional POC Self Test POC COVID Testing

#### Growth in rapid testing

- Growing demand for reliable, rapid and decentralised diagnostic testing for patients at POC and in their homes
- While Central Lab testing currently accounts for approximately half of the market, professional POC is well established, and home testing is the most rapidly growing market segment
- Point-of-Care Diagnostics Market estimated to be worth USD50Bn by 2025\*\*
- Key stakeholders now on board with telehealth and rapid testing providers, consumers, regulators and investors \*\*

#### **Investment increasing**

- Most large IVD companies have COVID cash-cow businesses well funded post-COVID, with increased capacity and seeking to support further growth, with a noticeable increase in transaction activity
- eHealth businesses (telehealth and eCommerce) are expanding rapidly and seek new products and services that meet growing consumer needs

\* Lumira DX Diagnostic opportunity analysis, Investor presentation July 2021

\*\* McKinsey & Co, Telehealth: A quarter-trillion-dollar post-COVID-19 reality? May 2021

## EXPANDING DEMAND FOR OEM SUPPLY

Post COVID, Atomo is actively engaging with a receptive diagnostic market



Atomo's booth at AACC in Chicago, July 2022

#### **Resurgent Interest in New Products and Home Testing**

- Atomo has seen an increase in enquiries and interest in new test development alongside a significant market increase in point of care and home-based testing post pandemic
- Recent engagement with the market, most recently at AACC and the Next Gen Dx conferences in the US, is raising awareness of Atomo in the industry, and provides the company with confidence in the commercial opportunities open to its blood and swabbased solutions. Recent market engagement also generates an extensive list of potential new channel partners and customers

#### Scalable Solutions

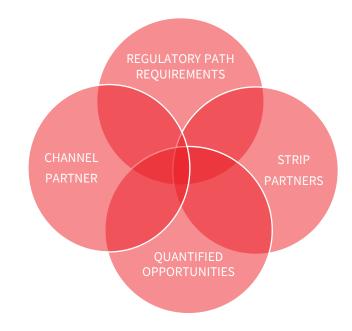
• With existing in-market products and customers, regulatory approvals and established production all demonstrated, Atomo's products are well positioned to establish themselves as a gold standard for usability in rapid testing and offer the company an opportunity to rapidly expand its customer base and applications menu through partnerships

# FINISHED PRODUCT STRATEGY

Over the last 6 months, Atomo has been focusing on development of a go-to-market and product partnership strategy involving a number of key elements shown

- Channel partner feedback on prioritisation of customer demand for at-home self test products, and identifying preferred product pipeline
- Progressing discussions on potential channel partner agreements to support commercialisation activity
- Reviewing and finalising industrial partners (assay and manufacturing infrastructure) to ensure robust supply chain and ability to execute and scale





# COMMERCIALISATION PRODUCT ROADMAP

Atomo has reviewed the changing point of care test landscape post pandemic, including engagement with emerging eHealth companies now opening up home based healthcare. This assessment of emerging product demand, technical feasibility, regulatory pathway and go-to-market channels is enabling the company to finalise it growth planning

The company now intends to bring to market during FY23 and FY24, in partnership with an established rapid test player, a number of home test and professional POC tests utilising Atomo's integrated cassette and digital solutions

#### **NEW FINISHED PRODUCTS PIPELINE:**

- hCG Pregnancy (Blood):
  - Anticipated launch in FY24
- Vitamin D, Thyroid (TSH) or PSA / Semi Quantitative
  - Pending review of market opportunity and regulatory pathways
- **OTHER APPLICATIONS:** Atomo is actively reviewing a number of other clinical applications for self-test and professional use in conjunction with potential industralisation partners



The rapid increase in telehealth clinical services in the home opens up opportunities for increased decentralised testing

# STRATEGY FOR FY23 AND BEYOND

Switching focus and investment from expansion of installed manufacturing capacity (now complete) to commercial scale up and business development, including focusing on:

- Expansion of senior commercial resourcing and associated engagement with market and channel partners
- Attendance at key industry conferences AACC, Next Gen Dx, Medica and Arab Health
- Refreshed marketing, collateral and increased promotion website, materials, videos.
  - Atomo video: <u>https://www.youtube.com/watch?v=RVA3BBcOUP4&t=23s</u>

Scale up of Atomo's OEM customer base utilising our proven blood testing platforms, eHealth solutions and in future Atomo's swab device, across key OEM channels:

- Direct engagement and promotion to diagnostic companies
- Establish a number of reseller partnerships development companies with access to new test programs
- Explore adjacent market opportunities, including animal health

Commercialise a range of new Finished Tests for Home and POC market channels for the US market:

- A blood-based pregnancy test for home use as well as a screening test in A&E / Emergency
- An App/reader supported semi-Quant test for home monitoring
- A swab-based test utilising the Atomo swab device (once commercialised) applications of potential interest include COVID / Flu A & B combo plus a number of STI's



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### APPENDIX

23 AUGUST 2022

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# OUR TEAM

### Board

### John Keith

#### Non - Executive Chair

Mr. Keith is one of the Managing Directors at BNP Paribas, establishing and leading its financial institutions coverage team. Prior to that, he led management and coverage roles for Nomura Securities in Sydney and Hong Kong. His career comprises working with supranational, sovereign and institutional clients across all areas of investment and institutional banking Mr. Keith has also served as a Director of ASIA Limited, Calliva

Limited, Room to Read Australia Foundation and Ascham Foundation.



#### Dr. Curt LaBelle

#### Non - Executive Director

Dr. LaBelle has been actively involved in the healthcare industry for 20 years, both operationally and as an investor. He is the Managing Partner at the Global Health Investment Fund, JP Morgan and others. He also serves as a director on the boards of Alydia Health, Atticus Medical and Eyenovia. Prior to joining GHIF, Dr. LaBelle was Managing Director at Tullis Health Investors and

Vice President at Investor Growth Capital.



#### Non - Executive Director

A veteran of the life sciences industry building market-leading global businesses, Ms. Neff is the Non-Executive Director of Cytek Biosciences Inc. Non-Executive Director of Guide Dogs For The Blind Inc. As principal of DJN Consulting, LLC, Ms. Neff works with several healthcare startup companies providing strategic business advice to and mentoring the executive management team.

Previously CEO of Evanostics, LLC., Pathwork Diagnostics Inc., and COO at Complete Genomics Inc., following a 15year career with Becton Dickinson Inc.



#### Non - Executive Director

Dr. Kasian is the Chair of IODM Limited. Non-Executive Director of Eco Systems Ltd (ASX:ESL). Executive Chairman of Zucero Therapeutics Limited. Previously Chair and CEO of Genetic Technologies Limited. Dr. Kasian holds a 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.



ATOMO DIAGNOSTICS LIMITED | (ASX: AT1)

# OUR TEAM

### Executive Team

### John Kelly

### Founder, Managing Director and CEO

Before founding Atomo Diagnostics in 2010, Mr. Kelly was Chief Operating Officer at ASX listed (subsequently NASDAQ listed) Unilife Corporation, where he oversaw the development of the award winning Unifill device, licensed to Sanofi Aventis. Previously, Mr. Kelly led the New Product Implementation Group at ResMed and commercialised the market leading Swift mask system.

In addition to his commercial experience, Mr. Kelly is a Graduate of the Australian Institute of Company Directors.



#### Will Souter

#### **Chief Financial Officer**

Experienced senior finance executive, lawyer and investment banker. Prior to joining Atomo, Mr. Souter was Chief Financial Officer for property and construction tech company, Verton Technologies. Previously Executive Director at RFC Ambrian. Mr. Souter was also a Director at PwC over a 10-year period in London and Sydney and worked at Minter Ellison Lawyers. Mr. Souter is a graduate of the

Australian Institute of Company Directors and has been admitted to the Supreme Court of NSW.

### Chandra Sukumar

#### **Chief Operating Officer**

Ms. Sukumar joined Atomo in 2017 as Director of Programs, bringing with her more than 25 years of experience within the medical device industry. She has extensive experience in the development of consumer medical devices from conception to commercialisation. Prior to joining Atomo, Ms. Sukumar served in a variety of leadership roles within ResMed, including supply chain management, global manufacturing.

and APAC marketing.



### Dr. Marilyn Clarke

### Director, Quality Assurance & Regulatory Affairs

Quality professional with over 20 years' experience, Dr. Clarke has extensive research and project management credentials in infectious disease and cancer research. Experienced with managing medical device manufacturing, quality control of pharmaceutical products and pathology testing laboratories. More recently, Dr. Clarke has focused on ensuring Atomo

Diagnostics has a robust Quality Management Systems meeting global regulatory standards.



## OUR TEAM

### Commercial Team

#### Jim McMenamy

### Head of Business Development and Partnerships -U.S.A

Mr. McMenamy has over 30 years of experience in the global POC diagnostics. He has held leadership roles in areas of Marketing, Sales, Business Development and General Management in global human and veterinary POC diagnostics markets for these organisations. Mr. McMenamy has extensive experience in the successful development and commercialisation of numerous

custom private label and company branded rapid diagnostic Lateral Flow and Molecular tests.



#### Anna Tucker

#### Vice President of Business Development - Europe

Ms. Tucker brings to Atomo a proven track record of developing businesses across the Life Sciences sector, with more than 25 years' experience working in sales, distribution management and field marketing globally. Ms. Tucker has previously held positions covering sales and marketing with a number of healthcare and technology companies globally. She brings to Atomo a wealth of experience in building and leading

commercial teams and distributors and has a proven track record delivering results to her companies and their partners.



#### Jason Kavanagh

#### Business Development Manager - APAC

Mr. Kavanagh is a life sciences professional with over twenty years' experience across; manufacturing (small molecule, biopharma & regenerative medicine), biotechnology, business development, scientific communication, digital transition and technical sales within the industry. He specialises in Go-to-market strategy, solution-based selling, business development, complex negotiations,

communication, SaaS & technical sales, client liaison, developing and driving relationships & creating partnerships.

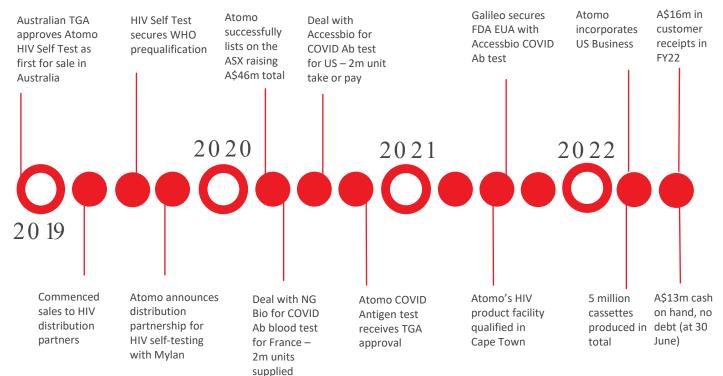
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# COMPANY HISTORY

- 2010: Atomo formed to address unmet user needs and reliability issues in point of care testing
- 2014: AtomoRapid awarded 'Best in Show' at Medical Design Excellence Awards (MDEA)
- **2015 / 2016**: US\$6m loan and US\$4m equity from Global Health Investment Fund (GHIF) + a US\$2.4m grant from the Gates Foundation
- 2016: First OEM Supply agreement signed with NG Biotech for a blood test for pregnancy
- 2017: Atomo HIV Self Test CE Marked by European regulators
- 2018: Atomo and Accessbio announce deal for HIV testing
- **2018:** Atomo and Owen Mumford partner for HIV Self Tests in Europe



### Recent Milestones

# PATENTED PORTFOLIO\*

#### 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.



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

A comprehensive Patent Report is available.

Atomo's patent portfolio focuses on integrated functionality necessary to perform a rapid diagnostic test in a point of care setting and the automating of steps of use to reduce errors and user complexity