PITT STREET RESEARCH

Atomo Diagnostics

User-friendly diagnostics

Share Price: A$0.019

ASX: AT1

Sector: Healthcare

26 February 2025

Atomo Diagnostics (ASX:AT1) develops unique 'user-friendly' Rapid Diagnostic Tests (RDTs). Atomo's technology was developed as a test device platform with the initial clinical application focused on HIV/AIDs where the first products were launched in 2018. The company is at a major juncture where it is building a more comprehensive pipeline. It has expanded registration of its HIV Self-Tests to more than 30 countries, is introducing a first in-market rapid test to detect active syphilis, developed with a partner, a new product for blood pregnancy testing that recently obtained CE Mark Approval, and expanded its OEM test cassette supply business so that its Pascal device supports US FDA 510k approval.

Atomo's growth has only just begun

AT1 has grown HIV test revenues nine-fold since Covid. Atomo's test device has been developed specifically to support self-testing. AT1 makes money both from selling tests as finished products or supplying assembled proprietary devices to diagnostic manufacturers who incorporate their own test strips into Atomo's user friendly cassette. One of AT1's commercial partners is Lumos Diagnostics, whose FebriDx test for acute respiratory infection was FDA-approved in 2023 and gained attractive US reimbursement in 2024.

Misperceived by investors

Since AT1's 2020 IPO, its shares have underperformed for a few reasons, including the reduced levels of COVID testing after 2022, the perception that blood-based diagnostic tests are being superseded by swab testing, and the perception that HIV is less of a problem now that therapies exist. Even though HIV is less deadly, there is still demand for testing, with governments actively procuring them to support national at-home testing programs. And even though Atomo's total revenue was inflated by Covid, its non-COVID revenues are several times ahead of pre-pandemic levels.

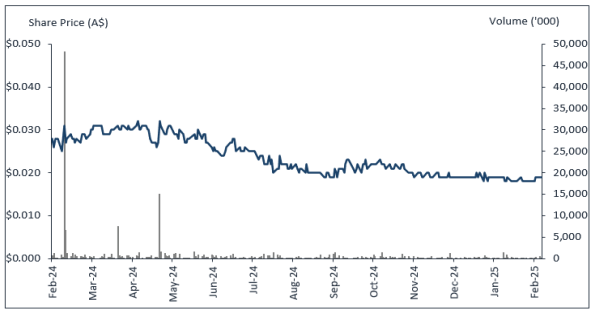
Valuation range of $0.056-0.08 per share

We value Atomo at $63.4m in a base case and $90.9m in an optimistic case, equating to $0.10 per share and $0.143 per share under the current number of shares on issue but amount to $0.056 per share and $0.08 per share when accounting for future dilution. We see potential for Atomo's shares to re-rate as the company takes a larger share of the market, commercialises its pipeline of new products and as it transitions to profitability. Please see page 26 for the key risks.

Market cap. (A$ m)	12.1
# shares outstanding (m)	639.2
# shares fully diluted (m)	647.6
Market cap ful. dil. (A$ m)	12.3
Free float	100%
52-week high/low (A$)	0.032 / 0.018
Avg. 12M daily volume ('1000)	609.1
Website	https://atomodiagnostics.com

Source: Company, Pitt Street Research

Share price (A$) and avg. daily volume (k, r.h.s.)



Source: Refinitiv Eikon, Pitt Street Research

Valuation metrics	
DCF fair valuation range (A$m)	63.4-90.2
DCF fair valuation (per share)	0.056-0.08
WACC	13.1%
Assumed terminal growth rate	2%

Source: Pitt Street Research

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Disclosure: Pitt Street directors own shares in AT1

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Introducing Atomo Diagnostics (ASX:AT1)

Atomo has been built on technology to make Rapid Diagnostic Tests (RDTs) very easy to use for the layperson.

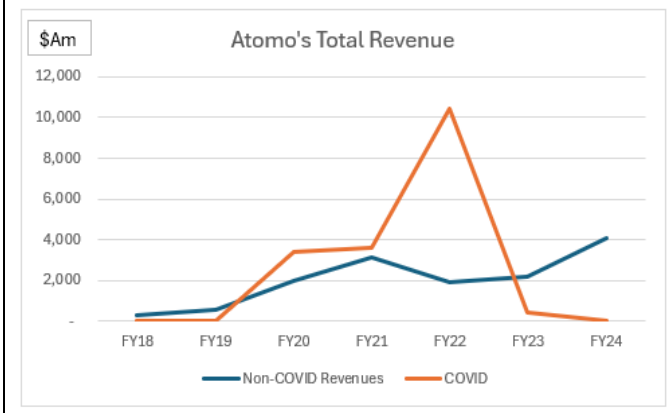
Atomo has been built on technology to make Rapid Diagnostic Tests (RDTs) very easy for both the clinician or the layperson to use without the errors common with existing 'chemistry set' test formats. Its flagship OEM platform Pascal is user-friendliness personified, in contrast to the kind of complicated multi-component test kits usually deployed today, where there are multiple components and numerous steps to complete each test, and the resulting error rates are high and user satisfaction typically low.

Atomo was founded in 2010 by John Kelly, a former engineer and manager at ResMed. Early funding and support came from Sydney Angels, the Global Health Investment Fund and the Bill and Melinda Gates Foundation, and from Lang Walker. A HIV rapid test was developed in 2015 and in October 2017 it gained its CE Mark in Europe for both self-use and professional use, while in July 2019 the product secured World Health Organisation prequalification. The self-test gained regulatory approval from Australia's TGA in November 2018 while the professional test gained TGA approval in November 2020, albeit with very significant market restrictions not in place in any other market. It remains the only HIV Self-Test approved by TGA for use in Australia. Within three and a half years from initial commercialisation, over 550,000 Atomo HIV rapid tests were sold to distributors in multiple international markets, and direct to market in Australia, as the company sought to establish the test as a more reliable, user-friendly solution to testing for HIV.

During the pandemic, it was a case of making hay while the sun shines for Atomo, with its devices in high demand given the pressing need for blood based COVID antibody testing at the start of the pandemic. Indeed, the company announced an order of 550,000 blood test devices from NG Biotech just a day before its April 2020 ASX IPO, and less than a month before, an order of nearly 400,000. The COVID-19 antibody test gained TGA approval in August 2020.

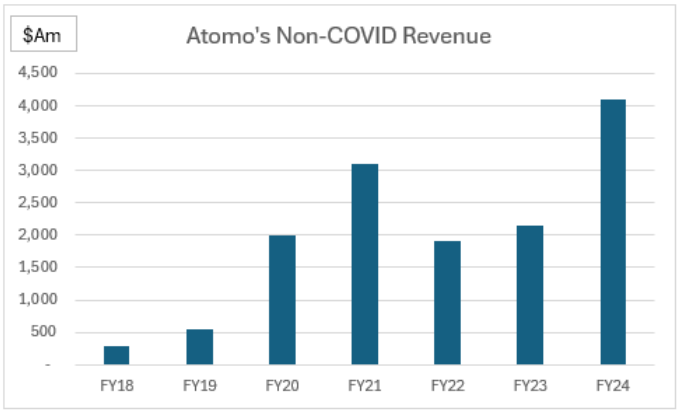
Atomo completed its IPO in April 2020 and was able to raise $30m at 20 cents per share. The shares rode the wave of enthusiasm during the pandemic, on the assumption that the pandemic would last for several years, that the main rapid testing used would continue to be blood-based antibody tests and that the company would benefit substantially for that. The company did derive substantial benefit - it derived $17m in revenue from COVID-19 tests between FY20 and FY22, which was more than double what it made from its non-COVID business (Figure 1 and Figure 2).

Figure 1: Atomo's Total Revenue



Source: Pitt Street Research

Figure 2: Atomo's Non-COVID revenue



Source: Pitt Street Research

Atomo's foray into COVID-19 antibody tests depicted that AT1's platform could be adapted for other health emergencies and established the viability and acceptability of home-based self-testing.

Although the demand for COVID-19 antibody tests waned quickly, Atomo's foray was not an entirely lost cause, because it enabled the company to show its platform could be adapted for other health emergencies. More importantly, the pandemic established the viability and acceptability of home-based self-testing as a key pillar of public and consumer health in the future. And, as we will outline in this report, there is still demand for HIV test kits, as evidenced by commencement post pandemic of government programs involving for the first time the procurement of Atomo's HIV self-tests, including Australia's $43.9m allocation in the most recent Federal Budget. Moreover, investors need only compare Atomo's revenues pre- and post-COVID to identify that demand has grown exponentially post-pandemic.

The key reasons to look at Atomo Diagnostics

1) **Atomo's solutions deliver superior rapid testing outcomes.** They are easy to use in centralised and decentralised settings alike, produce fast results (within 3 minutes), are easy to obtain and are affordable. They reduce common errors by around 90% when compared with multi-component kit formats. They are the only ones approved by the TGA and are superior to competitors that are approved in other jurisdictions in terms of reliability and user preference.
2) **Atomo is at the commercialisation stage and is undergoing exponential growth.** It commercialised its first tests back in 2017, and since then the company has sold over 7m platforms to date. The tests are approved in more than 40 countries. Its revenues have jumped from ~$500k five years ago to ~$4m today. We expect growth to continue over the next few years as demand for HIV test kits increases, and the company expands the capabilities of its technology to new clinical applications including Syphilis.
3) **The company has a strong ESG angle** playing a role in the gradual reduction of the presence HIV/AIDs and forming a part of government programs to this effect. State government have aims to achieve the virtual elimination of HIV transmission in 2025 and Atomo has supplied tests to government-funded vending machines nationally and has previously received several grants from governments and NGOs.

4) **Atomo has a high degree of commercialisation capability.** It boasts distribution agreements with Blooms the Chemist in Australia as well as its UK partner supplying the test to Boots and Tesco in the UK. It has US and European OEM customers for its Pascal cassettes. And it has low-cost research and manufacturing facilities in Australia and Cape Town.
5) **Atomos technology has potential for several future applications.** Atomo is branching out its platform technology to other indications, focusing initially on high value testing markets in sexual health and women's health.
6) **Atomo has strong IP protections**. It has over four dozen granted patents across several patent families in key geographic markets, including in the US, and across a wide range of applications – as outlined in Appendix I.
7) **The company is at a pivotal point**, being on the cusp of profitability, with revenues more than doubling over the last 6 half-yearly periods, at the same time its opex has come down by 30%. It is also branching out into new indications and repurposing its IP and functionality to deliver solutions for new adjacent market opportunities such as swab testing.
8) **Atomo's leadership team.** Founder John Kelly, who is also one of the company's largest shareholders with over 10%, remains CEO. Chairman John Keith has also been with the company since the early days, and the pair have led the company into the position it has reached today.
9) **We believe Atomo is undervalued** at its current market value which is less than $15m. We have valued the company at $63.4m in a base case and $90.9m in a bull case – equating to $0.10 per share and $0.143 per share respectively under the current number of shares on issue. These figures reduce to $0.056 per share and $0.08 per share when accounting for anticipated future dilution but still provide for a healthy premium to the current share price.

Overview of Atomo's diagnostic technology

In this section we will recap:

- The underlying science of Atomo's rapid diagnostic tests
- The platforms underpinning the tests
- How the test kits work in practice, and
- The advantages of Atomo's kits compared to competing technologies.

In later sections we will recap the indications Atomo is targeting – present and future; followed by its commercialisation plans, business model and market opportunity.

How Atomo's tests work

Atomo's tests are based on the lateral flow immunoassay but integrate key functionality in the test cassette which reduce the number of components and steps of use.

Atomo's Rapid Diagnostic Tests are based on the lateral flow immunoassay that has been standard in the diagnostics world since the 1980s. However, Atomo's technology and intellectual property relates to the integration of the key functionality needed to perform the test procedure directly into the test cassette. Its all-in-one format removes the need for accessories and reduces the steps of use as well as helping automate collection and delivery of blood and buffer to make testing more reliable and repeatable.

What is an immunoassay? An immunoassay is a diagnostic test for the presence of a specific substance. The test relies on the binding between an antibody and its target antigen to give a timely 'yes/no' answer. Immunoassays work in hours rather than days and can be made both highly specific in terms of detecting the antigen in question, and sensitive in terms of being able to detect the presence of small amounts of the antigen.

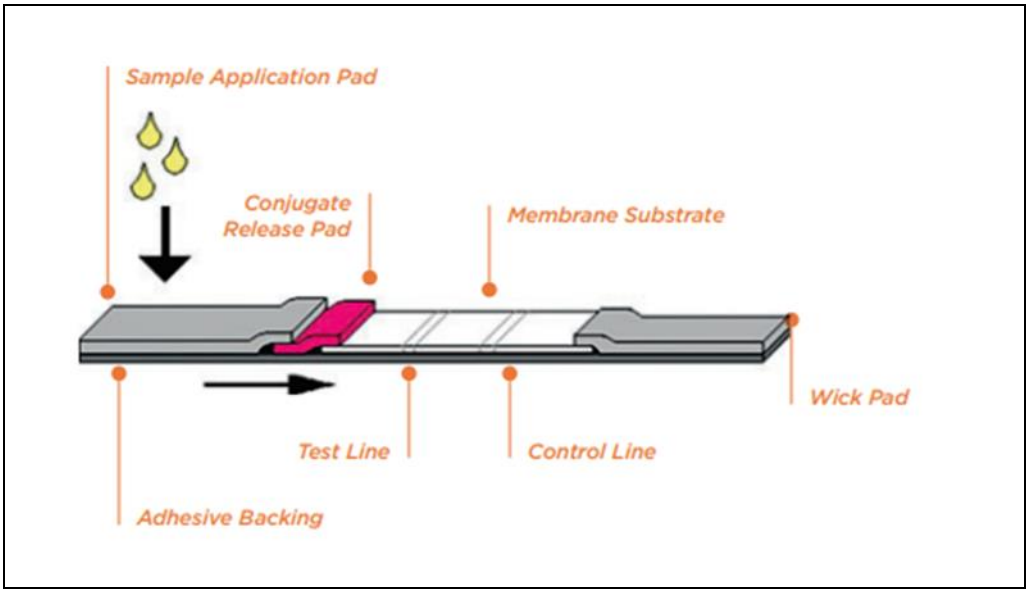
What is a 'lateral flow immunoassay'? A lateral flow immunoassay is a diagnostic where fluids from the sample being tested, as well as the various chemicals involved in the test, flow along a membranous strip[1] (Figure 3). In a line across that strip, called the 'test line', are placed the antigens representing the substance for which an assay is required, while slightly further up the test kit is positioned a line of human antibodies called the 'control line'. In a pad at the base of the strip is a reagent, that is, a substance used in a chemical reaction, which contains anti-human antibodies conjugated to a metal such as gold. Above that pad, called the conjugate pad, is the sample pad where the test user places the sample to be tested. The sample pad is placed so that when the sample to be tested is applied to the sample pad, the reagent in the conjugate pad turns to solution.

Together the sample and the conjugate antibodies then begin to flow along the membrane. Should there be antibodies to the antigen in the sample being tested, these antibodies bind to the antigen along the line where the antigen has been placed. In turn, the anti-human antibodies conjugated to gold bind to the antibodies in the sample. The gold makes for a visible red line where this binding takes place. Consequently, if red shows up at this line the result is positive. Part of the sample and the conjugate antibodies continue up the strip to the control line where the anti-human antibodies are bound by the human antibodies at that line. The result of all this will be either one or two red lines. A red line at both the test line and the control line mean that the test was positive, since there were antibodies to the antigen in the sample being tested which were caught by the antigens at the control line. If there is only one red line, it will likely be at the control line, meaning that the sample

[1] Made from a compound such as nitrocellulose.

and the conjugate antibodies didn't react with the antigens on the way up the membrane, leaving no gold bound to the control line.

Figure 3: How a lateral flow assay works in practice



Source: Company IPO prospectus

How long have lateral flow immunoassays been around? The first marketed lateral flow immunoassay was Unipath's Clearview home pregnancy test, launched in 1988. This test used lateral flow technology to detect pregnancy hormones in urine. The technology behind lateral flow immunoassays was first described in the 1960s, but Unipath's Clearview test marked the first commercial application of this technology.

Atomo's platforms

Atomo has five main platforms (Figure 4):

- **Pascal**, Atomo's original OEM platform.
- **Elion**, which is like Pascal but with optimised ergonomics to support self-test use with blood delivery. This test was designed to make self-testing as easy as possible. It was developed in part with grant funding from the Bill and Melinda Gates Foundation.
- **Galileo**. This is the company's ultra low-cost platform for HIV tests.
- **Curie**. This is a swab-based testing platform which Atomo will use to capture the large numbers of tests that are not blood-based. Swab based tests work with saliva and nasal fluid. It is named after famous European scientist Marie Curie.
- **Florey.** Like Pascal, this platform is designed to collect and deliver samples, along with integrated buffer delivery. It seamlessly integrates with standard lateral flow cassettes that are approved and available in the market, positioning it as an accessory that helps reduce the regulatory burden associated with the approved test.

Figure 4: Atomo's RDT platforms

ATOMORAPID RDT PLATFORMS	Integrated Lancet	Integrated Blood Collection	Integrated Buffer Delivery	LF Strip Compatibility
GALILEO 	●	●		●
PASCAL 	●	●	●	●
ELION 	●	●	●	●
FLOREY 		●	●	●
CURIE 			●	●

Source: Company

Atomo also has the **Da Vinci** platform, which is still in development. Da Vinci is intended to enable two rapid tests to be performed in a single rapid test procedure in the one device. This would be a genuine breakthrough once development is complete.

How Atomo's test kits work

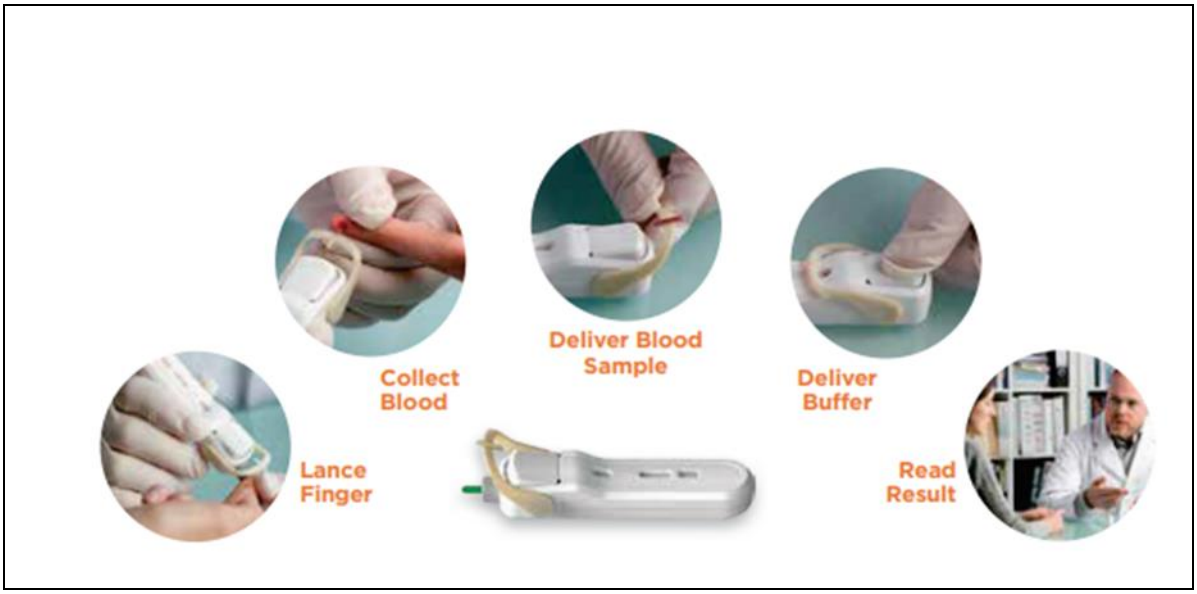
Atomo's tests have four key features:

1) **A built-in safety lancet**. Tests are designed so that the needle 'locks' in the device after every use, thus eliminating the risk of hazardous sharp injuries ensuing from the needle sticking out.
2) **A blood collection and delivery unit** that makes accurate collection and delivers the correct volume to run the test.
3) **An Integrated buffer delivery that enables button activated delivery of the precise quantity of buffer to the test strip.**
4) **Interlocked steps of use** that ensure that the user steps can only happen in the required sequence.

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

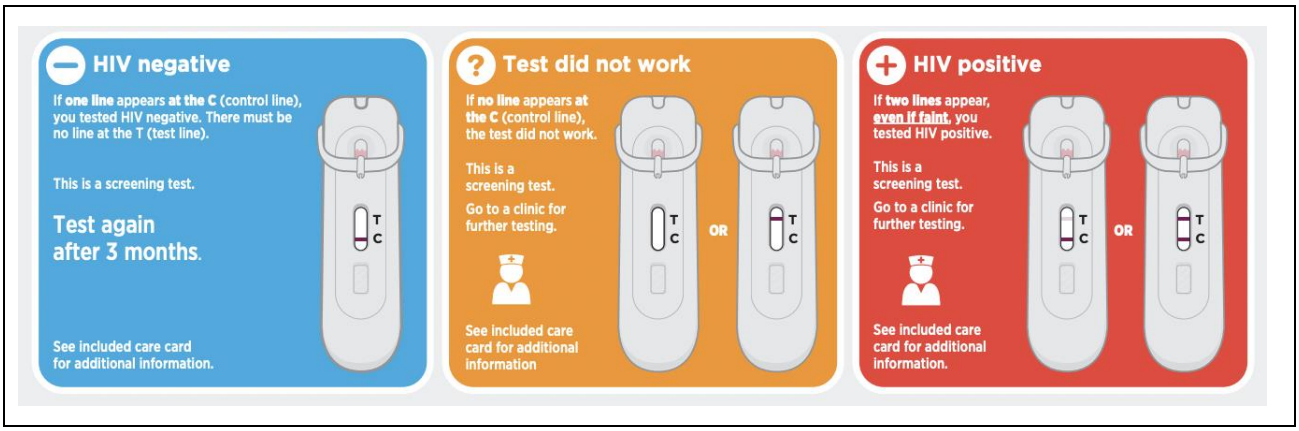
The device has been designed so that it doesn't activate until the proper steps have been followed in the right order. To create its diagnostics, Atomo developed its own proprietary 'blister' technology where buffer fluid is encased within a blister, sealed with a frangible seal. With Atomo the test process can be completed in just three simple user steps, with the result provided after 15 minutes (Figure 5 and Figure 6).

Figure 5: How Atomo's solutions work



Source: Company

Figure 6: How Atomo's tests deliver results



Source: Company

The advantages of Atomo's tests

Atomo's tests have several advantages. In particular:

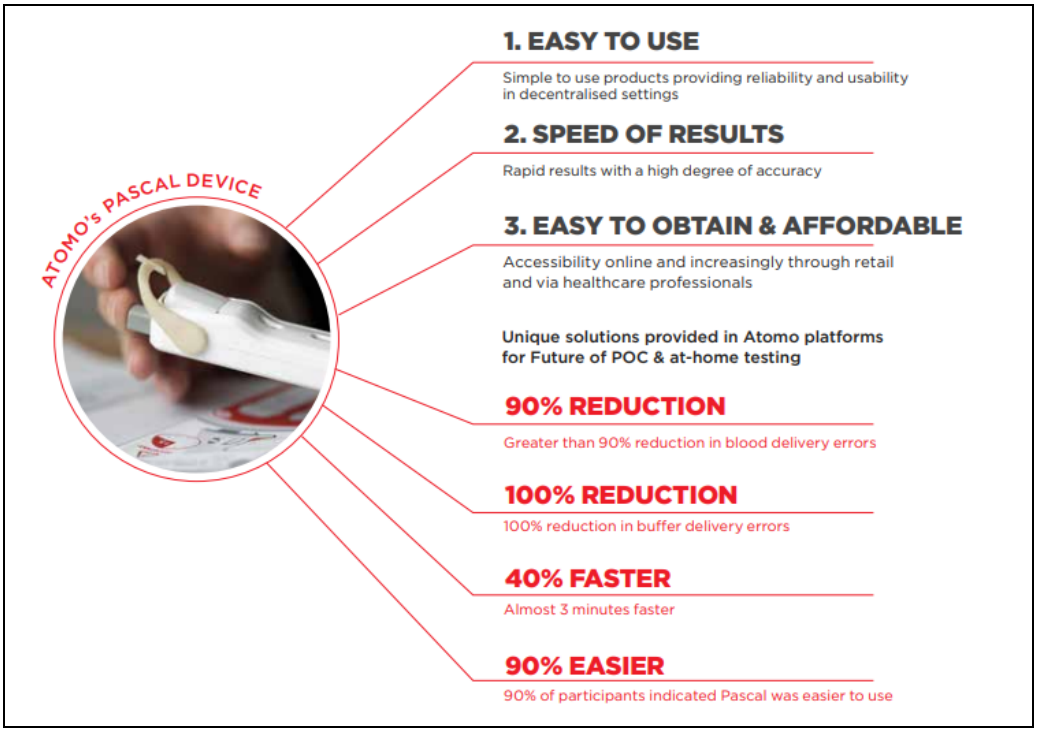
- They provide fast results (within 15 minutes)
- They provide improved performance when compared to standard multi-component test kit formats
- There is a 90% reduction in blood delivery errors
- 100% reduction in buffer delivery errors
- It takes 40% less time to perform a rapid test
- 90% of users prefer Atomo tests compared with multi-component kits; and

- They are affordable and easily accessible thanks to AT1's distribution agreements.

Atomo's tests are accurate, and demonstrably more user friendly than the competition.

The tests are easy to use in centralised and decentralised settings alike, produce fast results (within 5 minutes in the case of the NG Pregnancy test), are easy to obtain and are affordable (Figure 7). But most importantly, Atomo's tests are accurate. Sensitivity for detection of HIV is greater than 99% with the HIV Self-Test. Two French institutions - The Public Hopital Bicêtre and the Pasteur Institute - found that Atomo's Covid diagnostic had about 97% sensitivity and 100% specificity 15 days after the onset of symptoms. Atomo estimates that the error rate for first time users of its diagnostics is less than 3% and the overall error rate is less than 1%. By comparison, Atomo believes that traditional lateral flow diagnostics, which the company calls 'bits in a box', has a 10% error rate for healthcare professionals and 30% for laypeople. Atomo has also suggested that in customer surveys more than 90% say they prefer the Atomo product.

Figure 7: Advantages of Atomo's test kits



Source: Company

Atomo's pipeline

The Atomo early-stage pipeline is building out. Products currently in development include many new tests for new indications including for pregnancy and syphilis.

Curie: Atomo's swab testing accessory device

Atomo has developed a swab-reading device called the AtomoRapid Curie.

Atomo has developed a swab-reading device called the AtomoRapid Curie (Figure 8). It utilises Atomo's existing core IP and know-how to improve usability and performance of swab-based rapid tests. Swabs, taken from parts of the body with samples in question such as the nose, are inserted into the device and the sample is delivered to the cassette. The result is then deduced in a similar way to self-use rapid tests. It is compatible with existing rapid test cassettes and swabs, with Atomo's patented blister technology allowing for button activated mixing of buffer and sample.

Figure 8: The AtomoRapid Curie

Source: Company

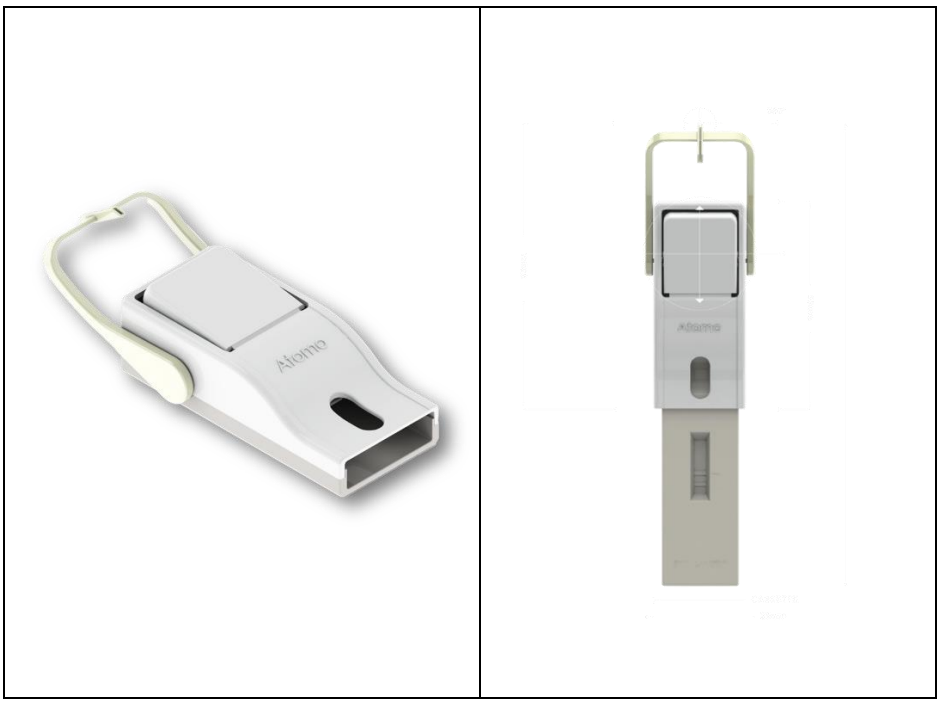
Florey: Atomo's blood testing accessory device

Florey is designed to collect and deliver samples, along with integrated buffer delivery. It seamlessly integrates with standard lateral flow cassettes that are approved in the market, positioning it as an accessory that helps improve usability and reliability while as an accessory reduces the regulatory and operational impact adopting the workflow with the approved test (Figure 9).

The production of the standard cassette in the foil pouch for existing products remains unchanged, with the Atomo sleeve added to the test at the point of use. This approach reduces the operational impact of adopting Atomo's best in class functionality, whilst maintaining the existing operational capacity for existing tests in the market. The standard cassette can be read visually in the Atomo sleeve of removed and inserted into existing POC desktop readers in the field.

The market opportunity is large. This segment accounts for a large part of the global point of care diagnostics market size, which is expected to reach USD 68.5 billion by 2030, registering a CAGR of 6.1% from 2024 to 2030.

Figure 9: The Atomo Florey device



Source: Company

Atomo's ground-breaking syphilis test

Atomo's syphilis tests will (crucially) be able to distinguish active infections and previously treated cases.

In mid-October 2024, Atomo secured a $2.44m Cooperative Research Centres Projects (CRC-P) grant to spearhead the development of a rapid test for active syphilis diagnosis. Syphilis is another sexually transmitted disease, caused by the bacterium *Treponema pallidum*. Atomo and the Burnet Institute had collaborated for several months prior to the October 2024 announcement, and the two parties are now working to complete development of a test,

which combines Atomo's Pascal cassette with a syphilis assay developed by the Burnet Institute.

Syphilis diagnostics have been around for a long time, but, crucially, the Atomo/Burnet test will be the first in market rapid test able to distinguish active infections and previously treated cases. Existing rapid tests only look for antibodies present in both active and prior infections, so are unable to distinguish the active syphilis from prior treated syphilis, significantly reducing their usefulness in screening. Moreover, there are no currently approved Syphilis tests approved for self-test use in Australia.

Atomo's pregnancy tests

Atomo's can detect pregnancy earlier because it can detect hCG in blood in only five minutes.

Most commercially available pregnancy tests analyse for human Chorionic Gonadotropin (hCG) in urine. Atomo's can detect hCG in blood in only five minutes. This is important because hCG shows up in blood in detectable quantities much earlier than in urine. Atomo's test can detect hCG levels below 13 mIU/mL in blood whereas early test detection urine tests work at more like 25 mIU/mL.

At first glance, you may think a blood test would be more 'invasive' and less desirable to use, which would negate its higher effectiveness from the user's point of view. It is not as if urine tests are completely ineffective. In fact, urine tests can be problematic, with insufficient or diluted samples affecting accuracy and generating false results. It has been long known that blood tests are more effective, the only thing stopping them from being widespread has been because you would have to send results off to a laboratory for analysis. With Atomo's kits…not any longer. You need only 10uL blood sample and the test result comes in just 5 minutes.

The product was developed with the French company NG Biotech which signed a commercial partner under a January 2023 agreement. NG had developed the assay and partnered with Atomo for user friendly delivery in the Pascal platform. It has been suggested that the blood-based hCG diagnostic can save up to 85 minutes in potential Emergency Room time. The product has gained CE Mark approval in Europe. Although it does not yet have FDA approval, the deal provides for Atomo to have exclusive rights to the US market[2].

Atomo's new test for alanine transaminase

In 2024 Atomo has started to talk about a new test for alanine transaminase (ALT), the liver enzyme that is often measured in blood tests to assess liver health[3]. Elevated ALT levels can indicate liver damage or disease, however currently it is evaluated by lab-based diagnostics. The laboratory of Associate Professor David Anderson at the Burnet Institute has developed a new point-of-care immunoassay for alanine transaminase based on antibodies to one of two isoforms of ALT called ALT1[4]. This technology has already been launched as a conventional POC test by a Chinese company called Nanjing BioPoint Diagnostics and Atomo is now partnering with Burnet to adapt this immunoassay to its Pascal platform.

[2] See ASX announcement 18 January 2023.
[3] Alanine transaminase is sometimes called alanine aminotransferase. Alanine transaminase is more commonly used in the US, while alanine aminotransferase is more commonly used in Europe and other parts of the world.
[4] See Point of care assays, WO/2018/060904, invented by David Anderson, Mary Garcia Huy Van and Zhimei Zhang.

The need for a faster diagnostic is strong. Nearly 75% of all Medicare beneficiaries in the US undergo ALT on a regular basis[5], which is about 67 million people in the United States[6]. This reflects the fact that liver problems show up in a range of chronic health conditions such as hepatitis and cirrhosis, and the high prevalence of non-alcoholic fatty liver disease, which is north of 30% of the adult population globally. Any point-of-care diagnostic that can address this market will represent considerable savings in terms of efficiency. The utility of the Burnet/Atomo diagnostic relates to the need to monitor patients undergoing drug treatment where the drug may have liver toxicities. On one estimate, more than half of all drugs in clinical use have had reported cases of liver toxicity[7].

The ALT test will soon be evaluated in a Phase 3 study.

The ALT test will soon be evaluated in a Phase 3 study. Clinical studies of all sorts of pharmaceutical agents routinely measure ALT levels to ascertain that the compound being evaluated isn't causing liver damage. Atomo has noted that a 'global top five pharma company' will use this product in a Phase 3 trial in the US, and 20,000 tests have already been supplied.

Figure 10: Atomo's app

Source: Company

[5] Am J Clin Pathol. 2015 Sep;144(3):423-6.
[6] See data.cms.gov/
[7] Int J Mol Sci. 2016 Feb 6;17(2):224.

Atomo's app

Atomo has developed an app that connects to its diagnostics. Around 2020, Atomo developed a disposable clip-in reader that could measure line intensity, record time and place of test (Figure 10). That work has now evolved into an app that not only allows for more accurate reading but, importantly, allows for transmitting of accurate data to medical professionals. This plugs Atomo into the rise of telehealth that has been accelerated by the Pandemic.

The app eliminates common use errors such as the use of an expired test and not waiting for enough time to read the result. Digital animations of steps will further improve the ease of use and performance.

Forthcoming tests

Atomo has expressed interest in the commercial opportunity for tests that screen for or monitor"

- Serum ferritin to measure circulating levels of iron
- Vitamin D
- Testosterone
- Gonorrhoea and chlamydia

Atomo's partnership with Lumos Diagnostics

Lumos Diagnostics' FebriDx test is enabled by Atomo's Pascal platform.

Lumos Diagnostics gained FDA approval in July 2023 for its FebriDx professional use antimicrobial resistance (AMR) test. This test is enabled by Pascal. Atomo had started working with Lumos in 2019 to develop what became FebriDx. The test is the only rapid, all-in-one point-of-care test in the world that can distinguish a clinically significant acute respiratory infection (ARI) and differentiate viral from bacterial infections. Demand for the test is driven in part by the rising scourge of antimicrobial resistance. It is estimated that in 2019 that bacterial AMR was directly responsible for 1.27 million global deaths in 2019 and contributed to 4.95 million deaths. Published data has suggested a marked decline in antibiotic use with FebriDx (by 80%) and that the test has 99% accuracy.

FebriDx is Atomo's US predicate. Beyond generating earlier revenues, the July 2023 FDA approval of FebriDx now provides Atomo with a predicate device for future 510(k) approvals in the US market. This means Atomo's or partner's own tests could have a reduced pathway to market by demonstrating that the usability is substantially equivalent to FebriDx. It is no guarantee that Atomo will take this path or that it will succeed in proving substantial equivalence to the FDA, but its task is less complicated and less expensive than if had to seek approval for its own tests.

Lumos's new product could be significant for Atomo beyond the 510(k) because of the potential for a 'CLIA Waiver'. CLIA is the Clinical Laboratory Improvement Amendments, a suite of US Federal regulations enacted in 1988 that sets the standards for laboratory testing quality, safety, and accuracy. Often diagnostics are waived from CLIA by the FDA if they are simple to use and the risk of wrong results are low. Lumos announced in October 2024 that BARDA, America's Biomedical Advanced Research and Development Authority, would fund a clinical study by Lumos that would allow it to apply for a CLIA Waiver for FebriDx. The study would compare the results from trained versus untrained users. If Lumos gains a CLIA Waiver, it bodes well for

Atomo. Most testing labs in the US get most of their business by volume from CLIA-Waived work. Should Lumos be CLIA-Waived, it increases fivefold the number of testing labs that can use the test, which today is only cleared for 'moderate and high-complexity use' settings.

Also boding well for FebriDx is Lumos's obtaining of reimbursement for the device. The company announced in early December 2024 that America's Centers for Medicare and Medicaid Services (CMS), which decides pricing for those two government agencies, had price the relevant PLA code[8] at US$41.38 per test, effective at the start of 2025. This effectively allows the product to go commercial in America.

Atomo's market opportunity

The market opportunity for Atomo is strong, with the global lateral flow diagnostic market worth multiple billions of dollars before the Pandemic and remaining large even excluding the temporary inflation due to the COVID-19 pandemic.

HIV testing

Before we outline the market opportunity, we need to outline what HIV is and answer the question as to whether HIV testing is relevant in the context of declining transmission and rising treatment options.

What is HIV? HIV is a virus that attacks the body's immune system, specifically targeting and destroying CD4 cells (also known as T-helper cells), which are a type of white blood cell that plays a key role in fighting infections. It can be spread by unprotected sexual contact with an infected person or any exposure to infected bodily fluids like blood. While HIV infection can be controlled with antiretroviral therapy (ART), there is currently no cure. People with HIV can live long, healthy lives if they are diagnosed early and receive appropriate treatment. That said, HIV, if left untreated, a severely weaken the immune system, making the body more vulnerable to infections and diseases. HIV may evolve into AIDS (Acquired Immunodeficiency Syndrome). It is estimated that 39.9m people lived with HIV in 2023[9].

The HIV testing market was estimated to be US$2.4bn in 2023. The self-test market is only 20% but we see potential for this to increase.

How big is the HIV testing market? The testing market (both professional and self-use) generally was US$1.8bn in 2022 and is expected to rise to $2.4bn in 2023[10]. The self-test market is only about ~20% of this today but we see potential for self-testing to take a greater proportion of the market and Atomo to play a part of it. Looking at the market by test numbers, Atomo has estimated that there are ~3m tests used in Australia per-annum and that there were 500,000 in the UK in 2022. Despite the higher population, the UK and Europe are behind the adoption of self-tests, but this is increasing as mainstream channels adopt self-testing.

- **HIV testing is still important globally even after the development of treatments,** particularly Highly Active Antiretroviral Therapy (HAART). In 2023 it is estimated that around the world 1.3 million acquired HIV and around 40 million people were living with HIV[11]. The recent rise of PrEP, that is, Pre-Exposure Prophylaxis, which are drug regimens such as Truvada that prevent HIV infection, has increased

[8] PLA stands for Proprietary Laboratory Analyses.
[9] UNAIDS data.
[10] https://www.medicaldevice-network.com/features/the-rise-of-home-hiv-esting-and-its-future-market-role/.
[11] World Health Organisation data.

the demand for products like Atomo's as 'companion diagnostics'. The diagnostics are now available globally over the counter in places like Tesco and Boots in the UK and CVS in the US. But declining HIV numbers doesn't mean testing numbers will because not all people who test for HIV will necessarily have the virus HIV.

- **Public policy is frequently favouring government procurement of the tests,** as evidenced by support in Australia's 2024 budget – A$43.9m was allocated through better prevention, testing, workforce training and information. The goal is to eliminate transmission by 2030. The most at-risk will get free HIV self-test kits. The company anticipated $1.3m over the next 2 years.

Other initiatives include:

- NSW setting up government-funded vending machines and Atomo has supplied tests to them. NSW aims to achieve the virtual elimination of HIV transmission in 2025.
- The UK offering free HIV rapid tests to the public as part of National HIV Testing Week.
- The 'Together Take Me Home Program' where the CDC will provide US$41.5m to provide up to a million rapid home tests to communities with high HIV prevalence rates.

Other markets

AT1 could easily repurpose its technology for other indications, and potentially have first mover advantage.

Beyond HIV, AT1 could be even more lucrative markets before it. It could easily repurpose its technology for these indications, and potentially have first mover advantage.

- The **Syphilis test market** was US$1.2bn in 2023 and is expected to reach US$1.9bn in 2032, exhibiting a CAGR of 5.1% over 2024-32[12]. Like the HIV test market, the syphilis is expected to grow because of the development of rapid test options, particularly those that are available at online retail stores and in-store pharmacies. What's more is that syphilis is a major societal burden too with 8 million people having acquired it in 2022 according to the World Health Organisation. Although Atomo is some time away from having a syphilis test ready for commercialisation, it could have a first-moved advantage given that there are no tests on the market year.
- Atomo has told investors that **pregnancy tests** are a US$2.1bn market. It is a well-established market but is dominated by tests that use urine rather than blood. The NG branded version of the test has CE Mark Approval in the UK and Europe as well as ANVISA approval for Brazil.
- Meanwhile, FebriDx is a US$5.2bn market[13] as it targets **the global antimicrobial resistance market** rather than the market for any particular indication. FebriDx has regulatory approval in the USA, UK, Europe, Australia and Canada. Beyond the convenience of self-testing solutions, an increased number of bacterial infections due to growing antimicrobial resistance. In the US, 2.8m cases of antimicrobial resistance (AMR) occur per year and this could increase to 10m per year by 2050 if proper diagnosis and treatment of microbial infections are not implemented.

[12] https://www.imarcgroup.com/syphilis-testing-market.
[13] See Slide 10 of the 2024 AGM Presentation.

Atomo's commercial plan

Atomo has two business models. One is selling finished rapid diagnostic test products; the other is selling OEM tests to other diagnostic developers (and Lumos is one such company). Of its $4.1m in revenue, $3.2m was from finalised tests (exclusively HIV tests) and the balance was OEM Cassette sales, through collaborations with Lumos, NG and the Burnet Institute.

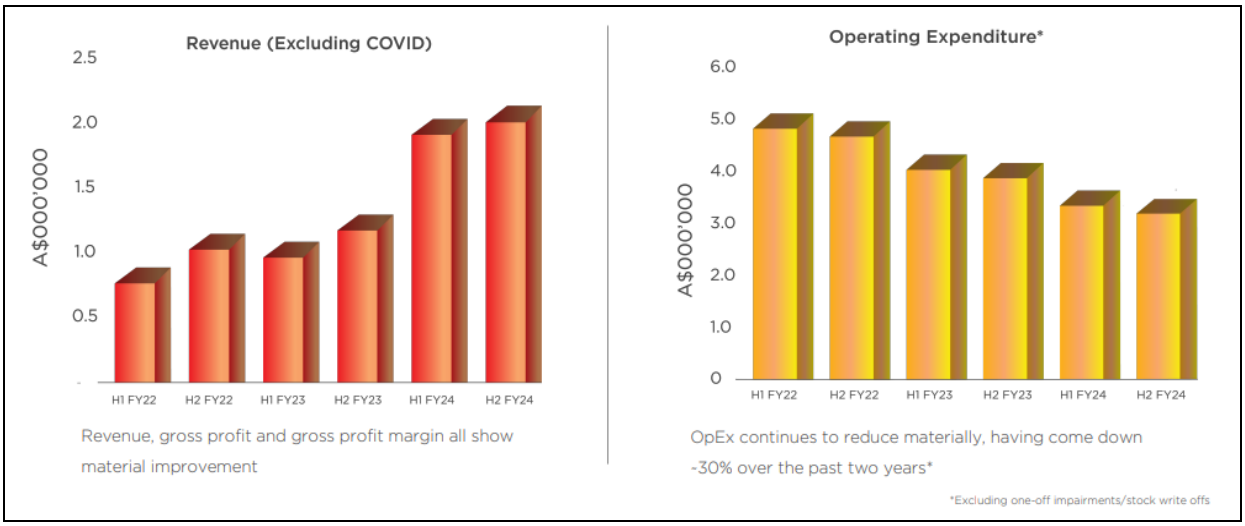
The company has a complete supply chain for product beginning with parts in China and packaging elsewhere in the world. Atomo has multiple distribution agreements in place for its own diagnostics including with Viatris and Newfoundland Diagnostics for HIV.

Pushing towards profitability

Atomo's sales have improved from $500k to >$4m in the last 5 financial years.

As we've already outlined in this report, Atomo is experiencing improved financial health with substantially growing revenues. Sales have improved from $500k to >$4m in the last 5 financial years and rose 60% in FY24 compared to FY23. The company is also improving its bottom line, having implemented measures over the last 18 months, resulting in a 30% reduction in underlying business costs (Figure 11).

Figure 11: Atomo's financial trends

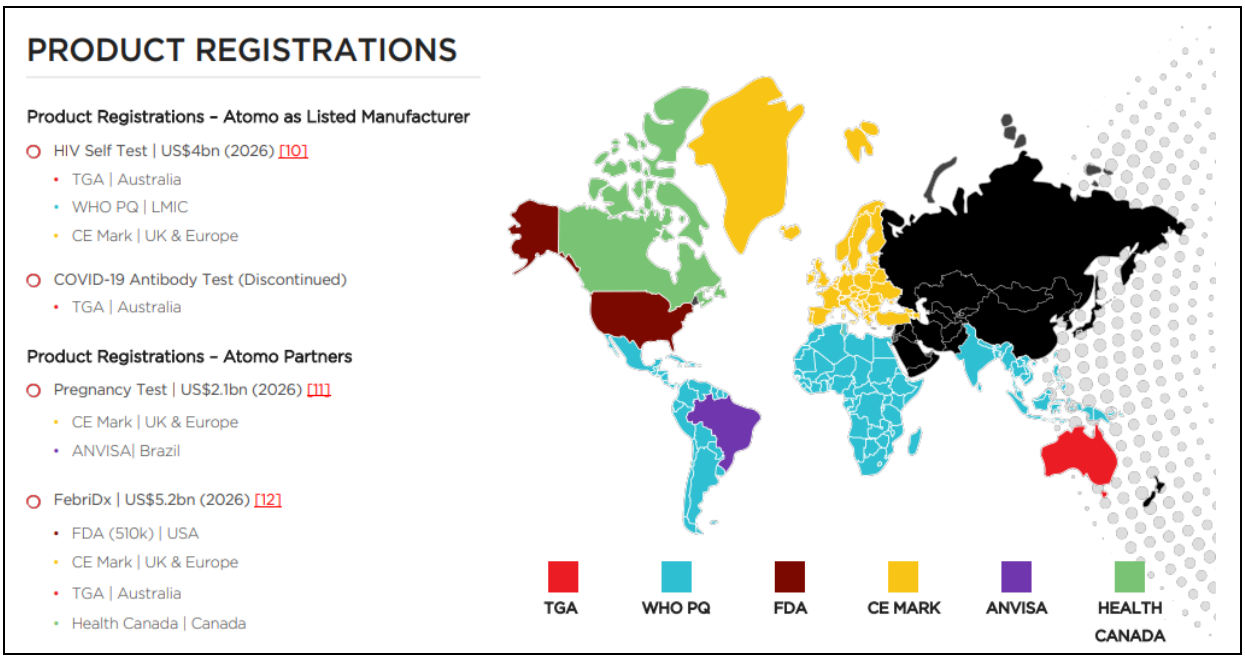


Source: Company

Product registrations

Atomo's flagship HIV Self-Test kits have TGA and CE Mark Approval. They also have WHO PQ (World Health Organisation Prequalification) status (Figure 12). It has undergone a screening program unique to the WHO to ensure it meets stringent global standards of quality, safety and efficacy. Products approved are eligible to be distributed in low-income countries.

Figure 12: Atomo's product registrations



Source: Company

Atomo's RDT products are manufactured under license by IDE Group, based a stone's throw away from Atomo's own office and overseas manufacturing in China and the USA.

Manufacturing

Atomo relies on third-party contract manufacturers. The RDT products are manufactured under licence by a company called IDE Group which is based in Sydney's inner west, a stone's throw away from Atomo's own office, and overseas manufacturing operations in Shenzen, China and Pennsylvania, USA. Cassettes are then shipped direct to Atomo customers. The HIV rapid test assay (test strips) is produced exclusively for Atomo by Lateral Flow Laboratories in Cape Town, South Africa. Atomo has set up its wholly owned packing and assembling facility in Cape Town next door to LFL to complete the final product assembly of the HIV product. All these facilities have been audited by the Australian Therapeutic Goods Administration (TGA) and the World Health Organisation and British Standard Institution (BSI).

Atomo's leadership team

The company's current board and leadership composition is as follows (Figure 13):

Figure 13: Atomo's leadership

Board of Directors	
Name and Designation	**Profile**
John Keith Chairman	Mr Keith has been Chairman of Atomo Diagnostics since November 2011. Keith has been Managing Director of BNP Paribas's Australia and New Zealand business since 2011, where he is also Head of Financial Institution Coverage. Prior to BNP Paribas he led management and coverage roles for Nomura Securities in Sydney and Hong Kong. Mt Keith has previously been a director of the Room to Read Australia Foundation and the Ascham Foundation. Keith has a Bachelor of Arts with Honours in Economy History from Victoria University of Wellington and a Master of Applied Finance from Macquarie University.
Paul Kasian Director	Dr Kasian has been a director of Atomo Diagnostics since February 2020 and of IODM Ltd (ASX: IOD) since September 2018. He was Chairman of Genetic Technologies (GTG) from February 2018 to September 2019 and a director from December 2013. Prior to 2016 Dr Kasian spent many years in financial services in asset management and senior executive roles. He was Chief Investment Officer at HSBC Asset Management, Head of HSBC Global Financial Team, a founding director of Accordius and a founding director of Wallara Asset Management. At Equity Trustees he was Head of Equities in 2013 and 2014 and Head of Asset Management from 2014 to 2016. Dr Kasian holds a PhD in Microbiology and an MBA, both from the University of Melbourne. He is a Graduate member of the Australian Institute of Company Directors.
John Kelly Founder and CEO	Mr Kelly founded Atomo Diagnostics in 2010 and remains its CEO. Before Atomo Diagnostics, Mr Kelly was Chief Operating Officer at Unilife from 2005 to 2008, where he led the 'Unifill' development team to develop the world's first glass prefilled drug delivery device with integrated auto retract safety feature. This technology was successfully licensed to Sanofi Aventis. Previously, Mr Kelly led the New Product Implementation Group at ResMed, where he managed the design and commercialisation of the ground-breaking Mirage Swift mask. Mr Kelly has a Bachelor of Engineering with Honours in Mechanical Engineering from the University of Liverpool, a Master of Science in Systems Engineering degree from Queen's University Belfast, and an Executive MBA from the University of Sydney, where he was awarded the Business School's inaugural 'Excellence in Leadership' scholarship.

Deborah Neff Director	Ms Neff has been a director of Atomo Diagnostics since September 2021. Ms Neff is a veteran of the Life Sciences industry building market-leading global businesses. Since 2020, Ms Neff has served as the Principal of DJN Consulting LLC, an executive management, business strategy and operations consulting company. Prior to that, from 2017 to 2020, she served as Chief Executive Officer of Evanostics LLC, an early-stage, private biotechnology company. From 2014 to 2016, she served as the Chief Operating Officer of Complete Genomics, a business unit of BGI-Shenzhen, a publicly traded genomic sequencing and proteomic services company. From 2006 to 2013, she was CEO of Pathwork Diagnostics, a privately held molecular diagnostics company, and from 2003 to 2006, she was CEO of Predicant Biosciences, a private biotechnology company. Ms Neff also served as President of BD Biosciences, a global business segment of Becton Dickinson, from 1995 to 2003. She served on the board of directors of Bio-Rad Laboratories from 2011 to 2017. She also serves on the board of directors of Guide Dogs for the Blind and on the advisory boards of privately funded start-up companies Wainamics and Partillion Bioscience. Ms Neff holds a Bachelor of Science in Physiology from the University of California, Davis and completed graduate training and licensure in clinical laboratory science. She has attended executive business programs in finance, marketing and general management at Wharton, Stanford and Harvard Business Schools.
Cheri Walker Director	Dr Walker has been a director of Atomo Diagnostics since November 2022. Dr Walker is an executive with more than twenty-five years of experience working with life science and diagnostic companies. Since May 2024 she has been CEO of Zeta Corporation. From September 2020 to November 2023, she was CEO of Rhinostics, an early-stage spin-out company based on technology initially developed at Harvard University. She has previously held senior executive positions at Abcam, Charles River Labs; Qiagen, and Life Technologies, now part of ThermoFisher. From 2000 to 2003 Dr Walker was an equities analyst at Deutsche Bank covering Life Science tools and services. Dr Walker holds a Bachelor of Arts in Biology from Swarthmore College and a PhD in Human and Molecular Genetics from Baylor College.

Source: Company

Atomo's peers

We have considered companies providing diagnostic tests for a variety of conditions, both on the ASX and on foreign exchanges. We did not limit our search to companies exclusively manufacturing tests, let alone companies exclusively focusing on HIV (Figure 14).

Figure 14: Atomo's peers

Company	Code	Location	Market Cap ($Am)	Website
Australian-Listed				
Imagion Biosystems	ASX:IBX	Melbourne, Australia	3.3	imagionbiosystems.com
Lumos Diagnostics	ASX:LDX	Melbourne, Australia	22.5	lumosdiagnostics.com
Proteomics	ASX:PIQ	Perth, Australia	80.6	proteomics.com.au
Rhythm BioSciences	ASX:RHY	Melbourne, Australia	26.4	rhythmbio.com
Uscom	ASX:UCM	Sydney, Australia	4.0	www.uscom.com.au
Atomo Diagnostics	**ASX:AT1**	**Sydney, Australia**	**12.1**	**atomodiagnostics.com**
Foreign-listed				
Abbott Laboratories	NYSE:ABT	Chicago, Il.	355,776.0	abbott.com
ASTA Corporation	KOSDAQ:A246720	Seoul, South Korea	78.6	astams.com
Biodyne	KOSDAQ:A314930	Seoul, South Korea	467.7	biodyne-usa.com
BioMerieux	ENXTPA:BIM	Lyon, France	22,430.5	biomeriux.com
Conavi Medical Corp	TSX.V:CNVI	Toronto, Canada	36.8	sunnybrook.ca
EKF Diagnostics	AIM:EKF	Cardiff, UK	216.6	www.ekfdiagnostics.com
OraSure Technologies	Nasdaq: OSUR	Bethlehem, Pa	460.4	orasure.com
Thermo Fisher Scientific	NYSE:TMO	Boston, Ma.	319,491.2	thermofisher.com

Source: Company

ASX-listed

Imagion Biosystems (ASX: IBX) is developing MagSense, a diagnostic imaging technology that can detect multiple oncology indications (in other words cancer). It is a reagent given to the patient and it involves the area of the body being scanned for a 'magnetic signature' and the physician sees a 'hotspot' image if a tumour is present.

Lumos Diagnostics (ASX: LDX) is developing its FebriDx professional use antimicrobial resistance (AMR) test, which is enabled by Atomo's Pascal platform. The test is the only rapid, all-in-one point-of-care test in the world that can distinguish a clinically significant acute respiratory infection (ARI) and differentiate viral from bacterial infections.

Proteomics (ASX: PIQ) is developing predictive tests based on its signature Promarker platform. The most advanced are PromarkerD for Diabetic Kidney Disease, PromarkerEndo for endometriosis and PromarkerEso for esophageal cancer.

Rhythm Biosciences (ASX: RHY) is developing cancer diagnostics. Its flagship technology, ColoSTAT is a 2nd generation multiplex assay designed to detect colorectal or bowel cancer. It is anticipated to be commercialised in 2025.

Uscom (ASX: UCM) has developed and commercialised medical devices that assist in diagnosing cardiac, vascular and pulmonary conditions. These include Uscom 1A that monitors cardiac blood flow, BP+ that measures blood pressure without invasive catheterisation, and SpiroSonic that aids ultrasounds.

Foreign listed

Abbott Laboratories (NYSE: ABT) discovers, develops, manufactures, and sells health care products worldwide including pharmaceuticals, Diagnostic Products, Nutritional Products, and Medical Devices. Relevant to Atomo, Abbott offers rapid diagnostics lateral flow testing products as well as molecular point-of-care testing for HIV, SARS-CoV-2, influenza A and B, RSV, and strep A; cardiometabolic test systems; drug and alcohol test, and remote patient monitoring and consumer self-test systems; and informatics and automation solutions for laboratories.

ASTA Corporation (KOSDAQ: A246720) engages in the development of diagnosis solutions in South Korea. The company offers microorganism identification systems, such as MicroIDSys and MicroIDSys Elite, which is used for applications in the areas of rapid diagnosis of infectious diseases, food hygiene management, agriculture and stockbreeding quarantines, and prevention of bioterrorism.

Biodyne (KOSDAQ: A314930) develops and manufacturers medical devices, reagents, and consumables in South Korea. It offers PATHPLORER LBC system instruments and reagents, as well as consumable kits. The company exports its products to Russia, Germany, Italy, Spain, Portugal, Poland, China, Taiwan, and Thailand.

bioMerieux (ENXTPA: BIM) develops and markets in vitro diagnostic solutions for the diagnosis of infectious diseases. The company's offerings include BACT/ALERT VIRTUO BACT/ALERT 3D, a blood sample culture system; BIOFIRE, a multiplex polymerase chain reaction (PCR) system; BIOFIRE SPOTFIRE Lowplex PCR point-of-care system. The company serves clinical and hospital laboratories, physicians, blood banks, vets, and industrial control laboratories.

Conavi Medical Corp (TSX-V: CNVI) focuses on designing, manufacturing, and marketing imaging technologies to guide common minimally invasive cardiovascular procedures. It offers Novasight Hybrid System, a system that combines intravascular ultrasound and optical coherence tomography to enable simultaneous and co-registered imaging of coronary arteries.

EKF Diagnostics (AIM: EKF) engages in the design, development, manufacture, and sale of diagnostic instruments, reagents, and other ancillary products. These include HemataStat II, a microhematocrit centrifuge that provides a quantitative hematocrit reading for blood samples. Additionally, it offers RaPET Serology immunoassay kits; QuStick Strep A for Strep A infection treatment; Altair 240 and Excel analyzers; Hema-Screen Serology, an analyzer dependent for early detection of colorectal cancer; and kits and other services related to COVID-19, as well as contract manufacturing solutions to third parties. The company was founded in 1990 and is headquartered in Cardiff, the United Kingdom.

OraSure Technologies (Nasdaq: OSUR). This company is best known for OraQuick, an at-home HIV test that detects HIV antibodies in oral fluid, but not saliva. That product was FDA-approved for use by medical professionals

in 2002 and for at-home use in 2012. The company also does tests for Hepatitis C, syphilis, Covid-19 and Ebola.

Thermo Fisher Scientific (NYSE: TMO) provides life sciences solutions, analytical instruments, specialty diagnostics, and laboratory products and biopharma services globally. Relevant to Atomo is Thermo Fisher's Specialty Diagnostics segment which offers liquid, ready-to-use, and lyophilized immunodiagnostic reagent kits, as well as calibrators, controls, protein detection assays, and instruments; immunodiagnostics develops, manufactures and markets complete blood test systems to support the clinical diagnosis and monitoring of allergy, asthma and autoimmune diseases; dehydrated and prepared culture media, collection and transport systems, instrumentation, and consumables; human leukocyte antigen typing and testing for organ transplant market; and healthcare products

Valuation and catalysts

We value Atomo at $63.4m in a base case scenario and $90.9m in an optimistic (or bull) case scenario. These amount to $0.056 in our base case and $0.08 in our bull case, accounting for future dilution.

We value Atomo at $63.4m in a base case scenario and 90.9m in an optimistic (or bull) case scenario. With 634.7m shares on issue, these amount to $0.10 per share and $0.143 per share (Figure 15). However, we have assumed the company raises $10m in capital at some point in the next couple of years to fund capital expenditure to cope with anticipated increase in revenue. For conservatism's sake, we assumed capital is raised at 2c per share and this generates 1.13bn shares on issue, reducing the price per share to $0.056 in our base case and $0.08 in our bull case (Figure 16).

Figure 15: DCF calculation (pre-dilution)

Valuation (A$m)	Base Case	Bull case
Present Value of FCF	22.3	36.0
Present Value of Terminal Value	36.1	40.9
Enterprise Value (A$ m)	**58.4**	**85.9**
Net (debt) cash (FY25 estimate)	5.0	5.0
Equity value (A$ m)	**63.4**	**90.9**
Share outstanding (Diluted)	634.7	634.7
Implied price (A$ cents)	**0.100**	**0.143**
Current price (A$ cents)	0.019	0.019
Upside (%)	426.0%	654.0%

Source: Pitt Street Research

Figure 16: DCF calculation (post-dilution)

Valuation (A$m)	Base Case	Bull case
Present Value of FCF	22.3	36.0
Present Value of Terminal Value	36.1	40.9
Enterprise Value (A$ m)	**58.4**	**85.9**
Net (debt) cash	5.0	5.0
Equity value (A$ m)	**63.4**	**90.9**
Share outstanding (Diluted)	1,134.7	1,134.7
Implied price (A$ cents)	**0.056**	**0.08**
Current price (A$ cents)	0.019	0.019
Upside (%)	194.2%	321.8%

Source: Pitt Street Research

Our assumptions

- **Revenue model.** We have modelled revenues from HIV tests and royalties from FebriDx with Lumos Diagnostics and Pregnancy test kits with NG Biotech. In the latter two instances, we assume Atomo received 15% royalties. We base sales off our assumptions of the market size and penetration.
- **Market size penetration.** For HIV, we assume the market is US$2.4bn (going off our assumption based on total spending outlined earlier in this report) and grows 2% per annum. We estimate, based upon Atomo's FY24 sales, that the company has an 0.11% market share, but that this gradually increases to 1% over the life of our model. For FebriDx, we assume revenues start flowing in FY25 and in FY26 for pregnancy tests. We assume a gradual ramp up to 1% over time.
- **Expenses.** We model cost of sales as a percentage of revenues. This was 60% in FY24, but we model a gradual decline to 45% over the life of our model. We assume a 10% decline in general and administrative expenses in FY25 and then 3% growth thereafter. Employee benefits increase by 3% annually. Depreciating and amortisation is modelled as a percentage of the company's opening Property, Plant & Equipment and Intangible Books every year (30% and 11% respectively) which are slight reductions from previous years.
- **Margins.** We assume (organic[14]) cash flow positivity in FY26 and the company reaching its first positive NPAT in FY27 which would represent an 11% margin, gradually rising to 20% over the life of our model.
- **Discount rate.** We arrive at a WACC of 13.8%, reflecting a 4% risk-free rate of return, a 7% equity premium and a 1.4 beta. Figure 17 shows the sensitivity of our valuation to various WACCs.
- **Terminal growth.** We model a 2% rate.
- **Tax.** We assume a 30% corporate tax rate in line with the higher bracket in Australia. Although the company may end up paying less than this, using the higher rate accounts for rates in other jurisdictions the company will enter.

We also modelled a bull case which assumes:

- A slightly faster ramp up to the 1% market penetration.
- NPAT profitability in FY26 and an end-of-model NPAT margin of 24% as opposed to 20%.

Figure 17: Sensitivity analysis of DCF calculation (market cap, base case)

		WACC						
		10.8%	11.8%	12.8%	13.8%	14.8%	15.8%	16.8%
Terminal Rate	0.5%	82.2	73.0	65.4	58.9	53.3	48.5	44.3
	1.0%	85.0	75.2	67.1	60.3	54.5	49.5	45.1
	1.5%	88.1	77.6	69.0	61.8	55.7	50.5	45.9
	2.00%	91.5	80.2	71.1	**63.4**	57.0	51.5	46.8
	2.5%	95.4	83.2	73.3	65.2	58.4	52.7	47.8
	3.0%	99.7	86.4	75.8	67.2	60.0	53.9	48.8
	3.5%	104.7	90.1	78.6	69.3	61.7	55.3	49.9

Source: Pitt Street Research

[14] By which we mean without the help of new shares issued.

Catalysts for Atomo's re-rating

We see five factors that may cause Atomo to re-rate from here:

- Revenue increases and cost reductions moving the company towards profitability.
- CLIA waiver of the Pascal FebriDx test in the US market and subsequent commercial success for Lumos's FebriDx diagnostic.
- Increased pipeline of new products, specifically active syphilis.
- Licensing of those products to commercial partners'
- Regulatory approval of new products.

Risks

We see the following key risks to our investment thesis:

- **Regulatory risk.** The company's ability to commercialise its product is contingent on regulators maintaining approval where it already exists (including meeting ongoing regulatory compliance requirements) and giving approval to new products. A failure to give new products approval, or even a withdrawal of approval, could be catastrophic to its future ambitions.
- **Commercial risk**. There is the risk that the company may fail to execute its commercial objectives for a variety of reasons including:
  - i) An inability to secure and retain distributors for its products,
  - ii) A loss of customers,
  - iii) Market competition (particularly from tests that use saliva samples rather than blood[15]),
  - iv) An inability to manage its capital and operating expenses,
  - v) A failure to adequately protects its intellectual property rights.
- **Key personnel risk**: There is the risk the company may lose key personnel and be unable to replace them and/or their contribution to the business

[15] One is the OraQuick HIV Self-Test. It was FDA approved in 2012 and has grown to be one of the most popular rapid tests in the US, with its reliance on saliva rather than blood being one reason attributed to its popularity.

Glossary

Acute – Very serious, extreme or severe.

Acute respiratory infection – A serious respiratory infection.

Alanine Transaminase - an enzyme that's mainly found in the liver. High levels of ALT in a patient's blood may indicate damage or injury to the liver.

CE Mark – Certification that a product to be sold in the European Economic Area meets all the appropriate provisions of the relevant legislation to the product.

Ergonomics – The study of the interaction between people and other elements of a system.

Food & Drug Administration (FDA) – The USA's healthcare regulator.

Group B streptococcal infection - An infection caused by a common bacterium (group B streptococcus).

Human Chorionic Gonadotropin (hCG) - A hormone produced by the placenta during pregnancy. It's sometimes called the pregnancy hormone because of its unique role in supporting a pregnancy. HCG is found in a woman's urine or blood around 10 to 11 days after conception.

Immunoassay - A test that uses the binding of antibodies to antigens to identify and measure certain substances.

Lateral flow immunoassay - a paper-based platform for the detection and quantification of analytes in complex mixtures. The aim is to perform rapid on-site detection of target substances.

Original Equipment Manufacturer (OEM) – A manufacturer of components of another company's products.

Predicate Device - A medical device that may be legally marketed in the US and used as a point of comparison for new medical devices seeking approval through FDA's 510(k) premarket clearance pathway.

Pre-Exposure Prophylaxis - Drug regimens such as Truvada that prevent HIV infection

Sensitivity - A test's ability to designate an individual with disease as positive

Serum ferritin – A blood test that measures the level of ferritin, and thus the amount of iron in the bloodstream.

Swab - A test that checks for viruses and bacteria that cause respiratory infections. A sample is taken and analysed.

Syphilis – A sexually transmitted infection caused by the bacterium Treponema pallidum subspecies pallidum

T-helper cells - A type of white blood cell that plays a key role in fighting infections

World Health Organisation Prequalification – A WHO programme that ensures health products meets stringent global standards of quality, safety and efficacy.

Appendix I – Atomo's Intellectual Property

Atomo's intellectual property is covered by seven patent families:

- **WO/2011/026169**, Sample collecting device, priority date 4 September 2009, invented by John Kelly, Richard Sokolov, Ian Johnson, Ernesto Hueso Monis and Eric Siu.
- **WO/2011/113114**, Diagnostic system, priority date 19 March 2010, invented by John Kelly, Eric Siu, Alison Norcott, Christopher Dunn, Ian Johnson, Ernesto Monis Hueso and Richard Sokolov.
- **WO/2012/048388**, Sampling assembly, priority date 15 October 2010, invented by John Kelly, Richard Sokolov, Ian Johnson, Ernesto Hueso Monis, Eric Siu, Melody Shiue, Kamman Law and Johannes Behrisch.
- **WO/2015/075677**, Fluid control in integrated testing devices, priority date 21 November 2013, invented by John Kelly, Huw Wallis and Gianluigi Bortoluzzi.
- **WO/2018/085878**, Integrated fluid module and test device, priority date 11 November 2016, invented by John Kelly, Huw Wallis, Keith Bocchicchio and Shing Yan Kong.
- **WO/2019/071323**, Integrated blood test device, priority date 12 October 2017, invented by Will Postle, David Sutton, Martijn Gijzel, Doug Cusack, Barbara van de Sande and Benjamin Dawson.
- **WO/2023/028663**, Automated verification and guidance for test procedures, priority date 2 September 2021, invented by Rohit Ketkar, Chandra Sukumar and John Kelly.

Appendix II – Atomo's Capital Structure[16]

Class	In Millions	% of dully diluted
Ordinary shares	641,202,310	99%
Options	8,384,999	1%
Performance shares	0	0%
Fully diluted shares	649,587,309	

Source: Pitt Street Research

[16] 639.2 million shares on issue plus 2.0 million shares as per the Appendix 3B of 18 November 2024

Appendix III – Analysts' Qualifications

Stuart Roberts, lead analyst on this report, has been an equities analyst since 2002.

- Stuart obtained a Master of Applied Finance and Investment from the Securities Institute of Australia in 2002. Previously, from the Securities Institute of Australia, he obtained a Certificate of Financial Markets (1994) and a Graduate Diploma in Finance and Investment (1999).
- Stuart joined Southern Cross Equities as an equities analyst in April 2001. From February 2002 to July 2013, his research speciality at Southern Cross Equities and its acquirer, Bell Potter Securities, was Healthcare and Biotechnology. During this time, he covered a variety of established healthcare companies, such as CSL, Cochlear and Resmed, as well as numerous emerging companies. Stuart was a Healthcare and Biotechnology analyst at Baillieu Holst from October 2013 to January 2015.
- After 15 months over 2015–2016 doing Investor Relations for two ASX-listed cancer drug developers, Stuart founded NDF Research in May 2016 to provide issuer-sponsored equity research on ASX-listed Life Sciences companies.
- In July 2016, with Marc Kennis, Stuart co-founded Pitt Street Research Pty Ltd, which provides issuer-sponsored research on ASX-listed companies across the entire market, including Life Sciences companies.
- Since 2018, Stuart has led Pitt Street Research's Resources Sector franchise, spearheading research on both mining and energy companies.

Nick Sundich is an equities research analyst at Pitt Street Research.

- Nick obtained a Bachelor of Commerce/Bachelor of Arts from the University of Sydney in 2018. He has also completed the CFA Investment Foundations program.
- He joined Pitt Street Research in January 2022. Previously he worked for over three years as a financial journalist at Stockhead.
- While at university, he worked for a handful of corporate advisory firms

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