



ASX Announcement

October 29<sup>th</sup>, 2025

## Quarterly Activity Report Q1 FY26

### Atomo sees significant commercial progress in several strategic areas

- **FebriDx® submitted to US FDA for CLIA wavier, enabled by excellent Pascal performance;** with Pascal validated in US clinical trials as delivering greater than 99% concordance between trained and untrained users
- **Atomo receives purchase orders from Lumos totalling ~\$1 million** since the signing of the FebriDx agreement with PHASE, as Pascal scale up commences
- **Preliminary clinical data for Atomo's Pascal Active Syphilis test demonstrates market leading specificity,** positioning it to be the first rapid test capable of reliably distinguishing between active and prior treated infection at the point-of-care (POC)
- **HIV Self-Test channels expand** with the test being launched through the Chemist Warehouse ecommerce site in Australia and an order received from USAID for Ukraine
- **Atomo's Florey clip-in device presented at two US diagnostic POC conferences** as a user accessory developed for existing standard tests registered on market
- **Atomo receives a further ~\$1.3 million in new capital,** in closing out capital raise activities that commenced in May 2025. Capital to be used to meet working capital requirements and funding of ongoing business objectives
- **Revenue: \$680k (unaudited)** revenue in Q1 FY26, consisting of HIV test sales, OEM Pascal sales and development fees from new potential OEM customers.
- **Cash receipts:** Cash receipts were \$2.27m, comprising \$808k from customers, \$1.3m net of transaction costs in closing out capital raising activities and \$165k received from the CRC-P Active Syphilis grant, with **cash on hand at quarter-end of \$3.39m.**



**SYDNEY Australia, 29 October 2025** – Atomo Diagnostics Limited (ASX: AT1) (**Atomo**) is pleased to release its Appendix 4C and quarterly activity report for the three months ended 30 September 2025 (Q1 FY26).

### **OEM Pascal Supply Business:**

Pascal has demonstrated outstanding performance in US clinical studies for FebriDx's CLIA waiver program. With Pascal delivering greater than 99% concordance between trained and untrained users across the studies, Lumos submitting FebriDx to the FDA for CLIA waiver approval in August, with hopes of CLIA waiver being secured in the coming months.

- *“FebriDx® could be performed by untrained operators with low, and in our case, almost no risk of error” - Annie Bell, VP Medical Affairs at Lumos Diagnostics*

Lumos previously indicated that it expects the agreement with PHASE to generate FebriDx product sales of up to US\$313 million over the six-year term, assuming CLIA waiver is granted and contracted MOQ's achieved. Each FebriDx® test sold to Phase requires Lumos order a Pascal cassette, with Atomo receiving a percentage portion of the proceeds based on the transfer price of Pascal. The company anticipates a significant increase in demand from Lumos from Pascal in the coming years. Atomo is working on scale up activities for Pascal, with orders worth ~\$1 million already received from Lumos for Pascal cassettes since the agreement with Phase was signed in July.

FebriDx securing CLIA waiver in Pascal is also anticipated to provide a predicate pathway to assist other Pascal based applications to come to market in the US via CLIA waiver. CLIA waiver also supports Atomo's plans to register its own pipeline of finished tests in the US.

### **HIV Self-Test Business Growth:**

Atomo's HIV Self-Test was launched this month through Chemist Warehouses ecommerce site<sup>1</sup>, the leading online retail site for pharmacy products in Australia. International sales during the quarter included orders from USAID for Ukraine. A recent order worth \$140k was received from Newfoundland for tests for the UK market, with product feedback from Newfoundland's key retail customers being positive.

---

<sup>1</sup> <https://www.chemistwarehouse.com.au/buy/160466/atomo-hiv-self-test-1-pack>



## **Active Syphilis Test – ‘best in class’ clinical performance demonstrated**

In November 2024 Atomo executed a \$2.44 million CRC-P grant with the Commonwealth Government. These funds have enabled significant progress to be made towards development of a rapid syphilis test with an exclusive global licencing agreement signed with the Burnet Institute earlier this year.

Testing conducted by the Burnet Institute demonstrated compelling diagnostic performance of the Pascal Active Syphilis test developed jointly by Atomo and Burnet, with Sensitivity of over 95% and Specificity of 83% when distinguishing between Active and prior treated patients (current generation rapid Syphilis tests on market are not able to distinguish between these two cohorts, with Specificities ranging from 0%-55% in these cohorts). Specificity of the Atomo test among never infected patients was 99%.

The company attended the Australasian HIV&AIDS Conference in Adelaide to support ongoing public health engagement for its HIV Self-Test and to hold discussions related to planned clinical trials in Australia for the Active Syphilis test. There was significant interest in the self-test compatible Active Syphilis test at the conference given the increasing public health challenge with Syphilis and with the Australian Government having recently declared Syphilis a ‘*Communicable Disease Incident of National Significance*.<sup>2</sup>

Engagement with clinicians in the US and in Australia suggests support for an Active Syphilis test that could be deployed in decentralised settings and there was particular interest in the ability of the test to be used as Self-Test on Pascal, with use cases and testing populations closely aligned with existing self-test channels that Atomo has helped develop for HIV.

Atomo is now preparing to engage with key regulators including the Australian TGA, the US FDA and BSI for Europe as it prepares to carry out tech transfer activities for test strip manufacturing from Burnet Institute in Melbourne to Cape Town to support production builds for clinical trials expected to commence early next year. The company intends to carry out assembly of the Active Syphilis test at its low-cost certified facility in South Africa, where it already carries out HIV operations.

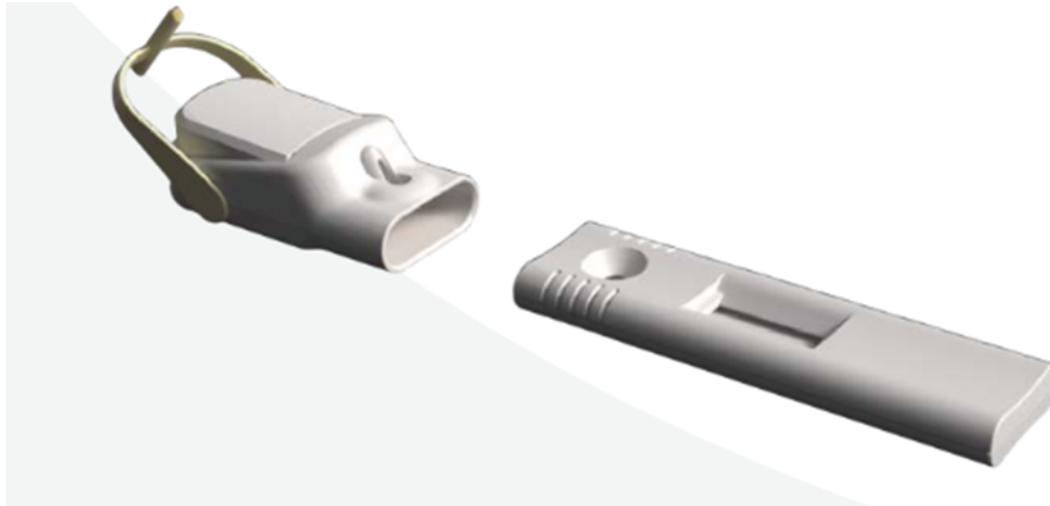
---

<sup>2</sup> <https://www.cdc.gov.au/newsroom/news-and-articles/syphilis-declared-cdins>



### **New Product Initiatives: Florey**

Florey utilises Atomo's existing IP and manufacturing processes and offers a simpler path to adoption as an accessory. The company presented Florey at the ADLM conference in July and at the ALF Conference in October with engagement underway with interested parties.



Florey has been developed specifically for adoption by companies with tests already approved and in-market, and the company believes that regulatory barriers to adoption of Atomo's technology as a user accessory will be reduced, and manufacturing operations for existing test cassettes unaffected. Atomo is now preparing to engage with key international regulators to define adoption requirements for Florey as a user accessory and has commenced production tooling to support device validation.

### **Board Changes**

Mr Patrick Cook was appointed as Atomo Chairman on 9<sup>th</sup> September having joined the Atomo board as a Non-Executive Director in May this year.

### **Financials**

Total revenue (unaudited) of \$680k for Q1 FY26, comprising \$450k of HIV test sales with the remaining amount coming from OEM Pascal sales and development & other fees. Operating costs for Q1 FY26 were \$1.3m (unaudited) reflecting a continuing focus on managing costs in the business. This is furthermore offset with CRC-P income recognised for Active Syphilis development of ~\$200k.



Cash receipts during the quarter were \$2.27m, comprising of \$808k receipts from customers, \$1.3m net of transaction costs in closing out capital raising activities from placement & SPP shortfall and \$165k from milestone payment received from the CRC-P Active Syphilis grant. Atomo finished the quarter debt-free, with **cash on hand at quarter-end of \$3.39m**, with an additional ATO rebate payment of \$875k for R&D investment receivable post quarter-end.

In accordance with ASX Listing Rule 4.7C.3, Atomo advises that an amount of \$135k was paid during the quarter to Atomo's Managing Director in salary and Non-Executive Directors in fees.

**Key Business Priorities FY26/27:**

The company set out its strategic priorities in Q4 FY25 update and continues to focus on key activities including growing its distributor network for HIV Self-Testing. An experienced Commercial Manager joining the team this month with this being a key area of initial focus.

Operational scale up of Pascal to support demand for FebriDx remains a key priority with CLIA waiver pending. The company is actively seeking new customers for Pascal in the US market, with FebriDx securing CLIA waiver being an important milestone in that process. Efforts to expand Atomo's OEM customer base also support promotion of Florey, which provides similar functionality to Pascal, whilst offering a reduced pathway for adoption with standard test cassettes already in-market.

Atomo is also seeking to expand its own portfolio of finished tests on Pascal with Active Syphilis and Blood pregnancy both offering potential in international markets, as well as a number of other applications under active consideration.



For more information, please contact

John Kelly

Atomo Diagnostics

[john.kelly@atomodiagnostics.com](mailto:john.kelly@atomodiagnostics.com)

Phone: +61 401 922 279

*This announcement was authorised by the Board of Directors.*

#### **About Atomo**

Atomo is an Australian medical device company supplying unique, integrated rapid diagnostic test (RDT) devices to the global diagnostic market. Atomo's patented devices simplify testing procedures and enhance usability for professional users and untrained self-testers. The Company has agreements in place for tests targeting infectious diseases including HIV, Syphilis, viral vs bacterial differentiation and pregnancy.

See more at [www.atomodiagnostics.com](http://www.atomodiagnostics.com).

#### **Forward looking statements**

This announcement may contain forward-looking statements which may be identified by words such as "believes", "considers", "could", "estimates", "expects", "intends", "may", and other similar words that involve risks and uncertainties. Such statements are not guarantees of future performance and involve known and unknown risks, uncertainties, assumptions and other important factors, many of which are beyond the control of Atomo or its Directors and management and could cause Atomo's actual results and circumstances to differ materially from the results and circumstances expressed or anticipated in these statements. The Directors cannot and do not give any assurance that the results, performance or achievements expressed or implied by the forward-looking statements contained in this announcement will actually occur and investors are cautioned not to place undue reliance on these forward-looking statements.

## Appendix 4C

### Quarterly cash flow report for entities subject to Listing Rule 4.7B

**Name of Entity**

Atomo Diagnostics Limited

**ABN**

37 142 925 684

**Quarter Ended ("current quarter")**

30 September 2025

<b>Consolidated statement of cash flows</b>	<b>Current Quarter A\$'000</b>	<b>Year to date (3 months) A\$'000</b>
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	808	808
1.2 Payments for		
(a) research and development	( 93)	( 93)
(b) product manufacturing and operating costs	( 1,052)	( 1,052)
(c) advertising and marketing	( 65)	( 65)
(d) leased assets	-	-
(e) staff costs	( 632)	( 632)
(f) administration and corporate costs	( 284)	( 284)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	19	19
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	165	165
1.8 Other (provide details if material)		
<b>1.9 Net cash from / (used in) operating activities</b>	<b>( 1,133)</b>	<b>( 1,133)</b>
<b>2. Cash flows from investing activities</b>		
2.1 Payments to acquire or for:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	( 9)	( 9)
(d) investments	-	-
(e) intellectual property	( 0)	( 0)
(f) other non-current assets	-	

## Quarterly cash flow report for entities subject to Listing Rule 4.7B

<b>Consolidated statement of cash flows</b>		<b>Current Quarter A\$'000</b>	<b>Year to date (3 months) A\$'000</b>
2.2	Proceeds from disposal of:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-
2.3	Cash flows from loans to other entities	-	-
2.4	Dividends received (see note 3)	-	-
2.5	Other (provide details if material)	-	-
<b>2.6</b>	<b>Net cash from / (used in) investing activities</b>	<b>( 9)</b>	<b>( 9)</b>
<b>3.</b>	<b>Cash flows from financing activities</b>		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	1,364	1,364
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	-	
3.4	Transaction costs related to issues of equity securities or convertible debt securities	( 63)	( 63)
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	( 51)	( 51)
3.7	Transaction costs related to loans and borrowings	-	
3.8	Dividends paid	-	
3.9	Other (provide details if material)	-	
<b>3.10</b>	<b>Net cash from / (used in) financing activities</b>	<b>1,249</b>	<b>1,249</b>
<b>4.</b>	<b>Net increase / (decrease) in cash and cash equivalents for the period</b>		
4.1	Cash and cash equivalents at beginning of period	3,220	3,220
4.2	Net cash from / (used in) operating activities (item 1.9 above)	( 1,133)	( 1,133)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	( 9)	( 9)

## Quarterly cash flow report for entities subject to Listing Rule 4.7B

Consolidated statement of cash flows		Current Quarter	Year to date
		A\$'000	(3 months) A\$'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	1,249	1,249
4.5	Effect of movement in exchange rates on cash held	64	64
4.6	<b>Cash and cash equivalents at end of period</b>	3,390	3,390

5. Reconciliation of cash and cash equivalents at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts		Current Quarter	Previous Quarter
		A\$'000	A\$'000
5.1	Bank balances	3,390	1,971
5.2	Term deposits	-	-
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
5.5	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>3,390</b>	<b>1,971</b>

6. Payments to related parties of the entity and their associates		Current Quarter
		A\$'000
6.1	Aggregate amount of payments to related parties and their associates included in item 1	135
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-

*Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments.*

## Quarterly cash flow report for entities subject to Listing Rule 4.7B

**7. Financing facilities**

*Note: the term "facility" includes all forms of financing arrangements available to the entity.*

*Add notes as necessary for an understanding of the sources of finance available to the entity*

	<b>Total facility amount at quarter end A\$'000</b>	<b>Amount drawn at quarter end A\$'000</b>
7.1 Loan facilities	-	-
7.2 Credit standby arrangement	-	-
7.3 Other (please specify)	-	-
<b>7.4 Total financing facilities</b>	-	-

**7.5 Unused financing facilities available at quarter end**

-
---

7.6 Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.

<b>8. Estimated cash available for future operating activities</b>	<b>A\$'000</b>
8.1 Net cash from / (used in) operating activities (Item 1.9)	( 1,133)
8.2 Cash and cash equivalents at quarter end (Item 4.6)	3,390
8.3 Unused finance facilities available at quarter end (Item 7.5)	-
8.4 Total available funding (Item 8.2 + Item 8.3)	3,390
<b>8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)</b>	<b>3.00</b>

8.6 If Item 8.5 is less than 2 quarters, please provide answers to the following questions:  
1. Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?

Answer: Not applicable.

2. Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?

Answer: Not applicable.

3. Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?

Answer: Not applicable.

**Compliance statement**

- 1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.
- 2 This statement gives a true and fair view of the matters disclosed.

Date: 29 October 2025

Authorised by: .....The Board  
(Name of body or officer authorising release see note 4)

**Notes**

1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.
2. If this quarterly cash flow report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report. If this quarterly cash flow report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.
3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.
4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the *[name of board committee – eg Audit and Risk Committee]*". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".
5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's Corporate Governance Principles and Recommendations, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.