



ASX Announcement

October 29th, 2024

Quarterly Activity Report Q1 FY25

Highlights

- **CRC-P Grant for \$2.44 million to complete development of a novel rapid test to detect active syphilis.** Atomo understands that the test would be the world's first rapid test specific for detection of active syphilis.
- **Revenue: \$876k (unaudited)** revenue in Q1 FY25, consisting of HIV test sales, OEM Pascal sales and Development fees.
- **Cash receipts:** Cash receipts from customers during the quarter of \$1.16m. Atomo finished the quarter debt-free, with **cash on hand at quarter-end of \$2.61m**, with an additional ATO rebate payment of \$753k for R&D investment received post quarter-end.

SYDNEY Australia, 29 October 2024 – Atomo Diagnostics Limited (ASX: AT1) (**Atomo**) is pleased to release its Appendix 4C and quarterly activity report for the three months ended 30 September 2024 (Q1 FY25).

HIV Self-Test Business

Atomo continues to see steady demand for its HIV Self-Test, and saw a pick-up during the quarter in orders received through the NAPWHA mail-home program, now funded directly by the Australian Federal Government. Atomo also received the first order of the Eastern European HIV Self-Test variant, with batch release to customer scheduled for November 2024. This reflects the expanding geographic footprint in Europe following success entering markets, such as UK and German pharmacy retail channels.

Atomo is on track to gain EU 2017/746 (IVDR) certification for its HIV Self-Test before the deadline of May 2025, with a successful first audit by BSI in South Africa complete and further audits scheduled for late November 2024 for the Sydney sites. A full dossier submission to BSI is planned for Q3 FY25 which will enable the company to continue to supply product into Europe/ UK while the IVDR dossier is under review.



Active Syphilis Test – Development Funded through a Government grant:

Atomo is the successful recipient of a \$2.44 million Cooperative Research Centres Projects (CRC-P) grant from the Commonwealth Government. Funds will complete the development of a groundbreaking rapid test for active syphilis on the Pascal platform. As previously disclosed to market, Atomo and the Burnet Institute have been collaborating for some time on the development of an easy-to-use test that distinguishes between active and prior treated Syphilis infection. Development of the test on Pascal also enables the test to be aimed at self-test users, significantly expanding the addressable market for the product. Atomo intends to execute the full agreement with the commonwealth in December, with initial funds anticipated from the grant in January.

Syphilis represents an increasing public health challenge globally, with WHO estimating that 8 million people acquired Syphilis in 2022¹. A recent report by the Kirby Institute indicated that rates of syphilis diagnoses in Australia have tripled over the last decade². Australia's Chief Medical Officer, Professor Paul Kelly, stated earlier this year that "the syphilis epidemic in Australia is past a tipping point...we must act now" echoing the gravity of the situation³.

In addition to the expanding use of rapid testing in public health channels, Atomo recognises the growing demand for STI testing via the consumer retail market and anticipates leveraging its existing commercial channels for the Atomo HIV Self-Test. Atomo's HIV rapid test is currently the only self-test approved for supply in Australia to partners such as Blooms the Chemist and is a leading test in the UK consumer market, available through Boots Pharmacies and Tesco Supermarkets. This emerging portfolio reflects Atomo's focus on sexual health tests that address both public health and consumer health demand, as well as representing a key segment in the growing self-test market.

¹ <https://www.who.int/news-room/fact-sheets/detail/syphilis>

² [HIV, viral hepatitis and sexually transmissible infections in Australia: Annual surveillance report 2023 | Kirby Institute](#)

³ [Australia's Chief Medical Officer calls on health professionals to combat syphilis | ASHM Health](#)



Liver function test (ALT) - Atomo is also collaborating with the Burnet Institute on the development of tests for monitoring Liver function (ALT). Atomo has received purchase orders related to product for a clinical drug trial in the US, with an initial batch delivered in October and a second larger batch due to be delivered to the US by December.

Other Opportunities: Atomo is now in active discussions with several test developers related to utilising Pascal across a range of target clinical applications, and we remain confident that the unique usability of our products will support the expansion of long-term supply agreement beyond our existing customer base.

Financials

Total revenue (unaudited) of \$876k for Q1 FY25, comprising \$635k for HIV test sales, and Pascal (OEM) sales of \$100k, with the remaining amount from development fees.

Operating costs for Q1 FY25 were \$1.6m (unaudited) compared to equivalent costs of \$2m for Q1 FY24, representing a reduction of 18% in Operating costs for the quarter, and reflecting the company's continued focus on managing costs.

Cash receipts from customers during the quarter were \$1.16m, and Atomo finished the quarter debt-free and with **cash on hand of \$2.61m**. Since the end of the quarter Atomo received an ATO rebate payment of \$754k for R&D investment made during the FY24 period.

In accordance with ASX Listing Rule 4.7C.3, Atomo advises that an amount of \$230k was paid during the quarter to Atomo Directors in salary and director's fees.



Key Company Priorities

- Continued growth of HIV sales by entering new markets and securing additional distribution channels, as well as a focus on promoting and scaling emergent public health-funded programs in Australia and assessing public health funded opportunities.
- Accelerate development of a novel rapid Syphilis test with partners, utilising CRC-P grant funding and leveraging off the existing technical and commercial work from other products to establish go-to-market channels for the product in both professional use and self-test variants.
- Support existing OEM partners Lumos and NG Biotech as they focus on expanding the marketing and sales of their rapid test products, and the scope of product approvals for test utilising Pascal, particularly in the key US market.

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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 supply agreements in place for tests targeting infectious diseases including COVID-19, HIV, viral vs bacterial differentiation and female health.

See more at 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 2024

Consolidated statement of cash flows	Year to date (3 months)	
	Current Quarter A\$'000	A\$'000
1. Cash flows from operating activities		
1.1 Receipts from customers	1,165	1,165
1.2 Payments for		
(a) research and development	(16)	(16)
(b) product manufacturing and operating costs	(962)	(962)
(c) advertising and marketing	(3)	(3)
(d) leased assets	-	-
(e) staff costs	(880)	(880)
(f) administration and corporate costs	(376)	(376)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	21	21
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	0	0
1.8 Other (provide details if material)		
1.9 Net cash from / (used in) operating activities	(1,051)	(1,051)
2. Cash flows from investing activities		
2.1 Payments to acquire or for:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	(12)	(12)
(d) investments	-	-
(e) intellectual property	(0)	(0)
(f) other non-current assets	-	-

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

Consolidated statement of cash flows		Current Quarter A\$'000	Year to date (3 months) A\$'000
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)	-	-
2.6	Net cash from / (used in) investing activities	(12)	(12)
3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	-
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	-	-
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	(46)	(46)
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (provide details if material)	-	-
3.10	Net cash from / (used in) financing activities	(46)	(46)
4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	3,688	3,688
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,051)	(1,051)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(12)	(12)

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

Consolidated statement of cash flows		Current Quarter A\$'000	Year to date (3 months) A\$'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(46)	(46)
4.5	Effect of movement in exchange rates on cash held	29	29
4.6	Cash and cash equivalents at end of period	2,608	2,608

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 A\$'000	Previous Quarter A\$'000
5.1	Bank balances	2,608	3,688
5.2	Term deposits	-	-
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
5.5	Cash and cash equivalents at end of quarter (should equal item 4.6 above)	2,608	3,688

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	230
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-
<i>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.</i>		

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

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

7.5 Unused financing facilities available at quarter end	-
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- 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.

8. Estimated cash available for future operating activities	A\$'000
8.1 Net cash from / (used in) operating activities (Item 1.9)	(1,051)
8.2 Cash and cash equivalents at quarter end (Item 4.6)	2,608
8.3 Unused finance facilities available at quarter end (Item 7.5)	-
8.4 Total available funding (Item 8.2 + Item 8.3)	2,608
8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)	2.50

- 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 2024

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.