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ASX Announcement **29 October 2020**

Quarterly Activity Report Q1 FY21

Highlights

- Continued strong customer demand driven by COVID-19 point of care antibody testing[1]
- Material new COVID-19[1] testing commercial developments set up potential for strong second half:
    - North America:
        - 2 million units take-or-pay (by 30 September 2021) agreement with Access Bio for use in combination with Access Bio's COVID-19 rapid antibody tests
    - Australia:
        - TGA approval for the sale of the AtomoRapid™ COVID-19 rapid antibody test for professional use secured in August;
        - rights obtained to distribute Access Bio's COVID-19 rapid antigen test;
        - TGA approval for the sale of Access Bio's COVID-19 rapid antigen test for professional use in Australia secured in October
    - India:
        - Agreement with DIVOC Labs for distribution of the AtomoRapid™ COVID-19 rapid antibody test
- Cash receipts from customers for the three-month period ended 30 September 2020 (Q1 FY21) of $3.04m, up 65% on Q4 FY20 ($1.84m), with the company cash flow positive for the quarter at the operating activity level, with net positive cash flow of $339k
- Atomo finished the quarter debt-free and with cash on hand of $26.3m
- Continued investment in R&D and manufacturing capacity to meet growing demand for Atomo's products , with total unit production capacity increasing to approximately 750,000 per month during the quarter and further expansion under way
- Revenues for Q1 FY21 (unaudited) approximately $2.5m

SYDNEY Australia Thursday, 29 October 2020 – Australian rapid blood test company Atomo Diagnostics Limited (ASX: AT1) (**Atomo**) is pleased to release its Appendix 4C and

[1] COVID-19 rapid testing detects SARS-COV-2, the virus that causes COVID-19

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quarterly activities report, covering the three-month period ended 30 September 2020 (Q1 FY21). Atomo achieved a number of material new COVID-19 commercial and regulatory milestones during the quarter and became cash flow positive at the operating activity level over the three-month period.

Atomo's co-founder and Managing Director John Kelly said, *"We are very pleased with the continued growth of the business and progress made during the quarter. We have continued to invest in our manufacturing capacity to support our customers by building out a robust supply chain. Our existing business continued to grow throughout the quarter across HIV, COVID-19 and other OEM diagnostic tests."*

"The agreements executed during the quarter for sizeable markets such as North America and India, with regulatory approvals obtained or pending, add significantly to the revenue potential of the business as we move into the second half of FY21. Our HIV and COVID-19 agreements now cover the most important markets globally. With the technology now proven, we are well placed to capitalise on increased market recognition and actively grow our OEM business in North America, while developing new Atomo finished products. We expect FY21 to be another transformational year for Atomo."

Material new COVID-19 commercial developments

In July 2020, Atomo and US partner Access Bio entered into a partnership agreement to expand access to COVID-19 blood-based rapid antibody testing to the North American market. Under the agreement, Access Bio is obliged to sell a minimum of two million products by 30 September 2021. If this sales threshold is reached, Access Bio's exclusive rights in the US, Canada and Mexico will automatically extend for a further 12 months with the same obligations and threshold as for the first year. Notably, the agreement is structured on an attractive revenue sharing basis and Atomo has co-branding rights on the product. Access Bio is in the process of seeking Emergency Use Authorisation (**EUA**) for the product from the US Food & Drug Administration (**US FDA**) with approval anticipated in Q2 FY21. Access Bio has placed an initial order for 259,200 Atomo devices to be used to build inventory of COVID-19 antibody tests in anticipation of US FDA approval.

In August, Atomo received TGA approval for its COVID-19 rapid antibody test, the AtomoRapid™ COVID-19 (IgG/IgM), for inclusion on the Australian Register of Therapeutic Goods (**ARTG**) for supply to departments of health, laboratories, medical practitioners and

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health care professionals in residential and aged care facilities in Australia. Atomo is in active dialogue with potential commercial partners including public health, corporate, aged care and other institutions and has product in-country to support initial sales efforts.

In September, Atomo entered into an agreement with DIVOC Labs for the non-exclusive rights to sell Atomo's COVID-19 rapid antibody test in India. India remains severely affected by COVID-19 and is pursuing a broad testing strategy in response that includes significant use of rapid antibody tests. DIVOC Labs has committed to an initial order of 77,000 units which will become effective upon receipt by DIVOC of regulatory approval of the product for professional use in India. This process is underway with AtomoRapid™ COVID-19 sample tests already in country and undergoing evaluation to support the regulatory process. Regulatory approval is anticipated to be received in Q2 FY21.

During September, Atomo expanded its partnership with Access Bio, with plans to launch a COVID-19 rapid antigen test in Australia, NZ and India. Atomo has secured the non-exclusive rights to market Access Bio's COVID-19 rapid antigen test in these markets under the Atomo brand. The US-made test has already secured an EUA from the US FDA and is CE Marked for professional use in Europe.

Post quarter end, Atomo received TGA approval for the COVID-19 rapid antigen test for inclusion on the ARTG for supply to departments of health, laboratories, medical practitioners and health care professionals in residential and aged care facilities in Australia. Atomo is now pursuing commercial channels for the product including via public health, corporate, aged care and other institutions. To ensure the professional delivery of rapid testing services to organisations where there is a need, Atomo has engaged Health Solutions Group Australia, a leading provider of professional healthcare workers across Australia, to provide the professional testing services to Atomo Customers.

Also post quarter end, Atomo's partner, Lumos Diagnostics raised $25 million in a pre-IPO funding round. Lumos exclusively uses Atomo's Pascal device for its FebriDx rapid blood test to detect bacterial or viral infection. Lumos has TGA approval for the test and is rolling it out across Australia. It is undergoing trials for FDA clearance in the US.

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Manufacturing scale up

Atomo successfully completed its first phase manufacturing expansion during the quarter, with total unit production capacity increasing to approximately 750,000 units per month from approximately 300,000 units per month in Q4 FY20. The next phase of capacity expansion is currently underway to increase total production capacity to approximately 1.3 million units per month, anticipated to be qualified and operational in Q3 FY21.

Atomo also committed to the expansion of its blister production capacity during the reporting period. The proprietary blister machines are an important, patent-protected asset that manufacture blisters for inclusion in Atomo devices to allow efficient and effective deployment of reagent to a test with the simple press of a button. In addition to direct investment in tooling, substantial investment was made during the quarter in design and functional upgrades to improve the capability of the second and subsequent blister manufacturing machines (categorised as Intellectual Property investment in the Appendix 4C and R&D in the Use of Funds summary in Appendix A). Construction of the second machine is expected to commence during Q2 FY21, with completion anticipated by the end of FY21. This additional capacity will bring Atomo's total device capacity across its key rapid test platforms to 1.6 million devices per month.

Financials

Cash receipts from customers in Q1 FY21 were $3.04m, primarily driven by receipts from sales related to COVID-19 antibody testing. The business was cash flow positive at the operating activity level with net cash flow of $339k.

Following strong revenue growth in FY20 ($5.4m reported), growth has continued into Q1 FY21 (unaudited) with sales of approximately $2.5 million.

Cash outflows for the quarter primarily related to building inventory levels, supply chain replenishment, investment in manufacturing and R&D.

Capitalised expenditure related to R&D (intangibles) of $997k, related largely to investment in the next generation blister machine development, as noted above.

In accordance with ASX Listing Rule 4.7B, Atomo advises that an amount of $135k was paid during the quarter to Atomo's Directors in salary and director's fees.

Atomo's cash balance at the end of the quarter was $26.3m

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Comparison of actual expenditure against use of funds statement

Appendix A provides a summary of actual expenditure, compared to the estimated use of funds set out in Atomo's IPO prospectus dated 4 March 2020 (**Prospectus**), in accordance with ASX Listing Rule 4.7C. Cash expenditure during the quarter was consistent with the use of funds set out in the Prospectus. Refer to the notes to the summary table in Appendix A for further information in relation to each of the categories of expenditure.

Outlook

Atomo continues to focus on core growth drivers, including:

- Obtaining regulatory approvals to facilitate commencement of device sales from key international contracts with Access Bio and DIVOC Labs for North America and India, respectively
- Pursuing opportunities in Australia for sale of a combination rapid COVID-19 screen (both antigen and antibody testing) into the local market
- Continued scale up of business in the HIV self-test market and in particular, supporting potential global tender opportunities being pursued by Atomo partner, Mylan
- Expansion of sales efforts related to OEM contracts, especially in North America to existing and new OEM customers
- Developing and expanding new Atomo rapid diagnostic finished products and entry into new point of care test markets, in partnership with certain existing customers in strategic channels
- Launch of Atomo's new digital health solutions that integrate with Atomo's devices, including a low-cost digital reader and a User App, to support the continued rollout of rapid testing in community and consumer settings

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This announcement was authorised by the Board of Directors.

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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, 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

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Appendix A

In accordance with ASX Listing Rule 4.7C Atomo provides the following use of funds information:

Use of funds	Prospectus	Actual Funds Deployed		Ref
		Actual Accumulated	As a % of Prospectus	
	(A$'000)	(A$'000)	%	
Expansion of Manufacturing & Distribution	11,700	711	6.1%	1
Research & Development and Product Commercialisation	11,025	1,623	14.7%	2
GHIF Loan Repayment (Including Outstanding Interest)	7,010	7,746	110.5%	3
Administrative Costs	2,446	349	14.3%	4
Market Expansion	1,600	106	6.6%	5
Interest on Convertible Notes	900	756	84.0%	6
Working Capital & Operating Costs	5,055	265	5.3%	7
Costs of the Offer	2,704	1,897	70.2%	8
TOTAL (INCLUDING EXISTING CASH)	**42,440**	**13,453**	**31.7%**	9

Ref	Comment
1	Capacity ramp up to support accelerated growth
2	Includes capitalised R&D related to blister machine design and engineering
3	Forex movements. No further outflows beyond Q4 FY20
4	Includes incremental public company costs
5	External expenses related to new market entry
6	Actual less than estimate due to IPO timing. No further outflows beyond Q4 FY20
7	Net working capital balance after accounting for outflows for operating costs and overheads and receipts of $4.9m from customers since IPO
8	Excludes cash outflows pre-IPO relating to costs of the offer amounting to $1.2 million. No further outflows beyond Q4 FY20
9	Total of $42.44m includes existing cash of $12.44m on hand as at 31/12 as per Prospectus. Total expenditure includes net working capital movements from 31/12 to IPO of $1.3m

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Rule 4.7B

Appendix 4C
Quarterly cash flow report for entities subject to Listing Rule 4.7B

Name of Entity	
Atomo Diagnostics Limited	
ABN	**Quarter Ended ("current quarter")**
37 142 925 684	30 September 2020

	Consolidated statement of cash flows	Current Quarter A$'000	Year to date (3 months) A$'000
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	3,036	3,036
1.2	Payments for		
	(a) research and development	(174)	(174)
	(b) product manufacturing and operating costs	(1,643)	(1,643)
	(c) advertising and marketing	0	0
	(d) leased assets	(1)	(1)
	(e) staff costs	(882)	(882)
	(f) administration and corporate costs	(132)	(132)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	39	39
1.5	Interest and other costs of finance paid	(1)	(1)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	96	96
1.8	Other (provide details if material)	-	-
1.9	**Net cash from / (used in) operating activities**	**339**	**339**
2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(83)	(83)
	(d) investments	-	-
	(e) intellectual property	(997)	(997)
	(f) other non-current assets	-	-

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) operating activities**	**(1,080)**	**(1,080)**

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	146	146
3.4	Transaction costs related to issues of equity securities or convertible debt securities	-	-
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	(25)	(25)
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**	**121**	**121**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	27,104	27,104
4.2	Net cash from / (used in) operating activities (item 1.9 above)	339	339
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(1,080)	(1,080)

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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)	121	121
4.5	Effect of movement in exchange rates on cash held	(139)	(139)
4.6	**Cash and cash equivalents at end of period**	26,345	26,345

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	26,345	26,345
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)**	**26,345**	**26,345**

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	183
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.

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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**	-

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)	339
8.2	Cash and cash equivalents at quarter end (Item 4.6)	26,345
8.3	Unused finance facilities available at quarter end (Item 7.5)	-
8.4	Total available funding (Item 8.2 + Item 8.3)	26,345
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	cash flow positive - N/A

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.

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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: 29/10/2020

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.

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