ASX Announcement **28 July 2020**

Atomo Diagnostics and Access Bio partner to expand access to COVID-19 blood-based rapid testing in North America

Atomo Diagnostics Limited (ASX: AT1) (Atomo) announces:

- ***Atomo executes agreement to enter the North American market***
- ***Revenue sharing on sales of finished products with a minimum sales commitment of 2 million units by 30 September 2021***

SYDNEY Australia, Tuesday, 28 July 2020 – Atomo has announced that it has signed a binding agreement with US-based diagnostics specialist Access Bio Inc. (KOSDAQ: 950130) (**Access Bio**) that will see Atomo supply its unique, integrated rapid diagnostic test (**RDT**) devices to Access Bio for use with its rapid test strip for detection of antibodies to COVID-19.

Finished products being commercialised under this agreement include a COVID-19 rapid antibody test for professional use and a COVID-19 rapid antibody test for self-test use (together, the **Products**). Once relevant regulatory authorisations or approvals are obtained, the Products will be launched in the United States, Canada and Mexico, co-branded by both Access Bio and Atomo, with Access Bio as the listed manufacturer. Access Bio will also have non-exclusive rights to sell the Products in the rest of the world with the exception of Europe, Australia/NZ and South-East Asia where Atomo already has contractual arrangements in place. Please refer to the announcement released to Atomo's ASX platform on 4 June 2020 for further details in relation to Atomo's existing contractual arrangements.

Under the agreement, Access Bio is obliged to sell a minimum of two million Products by 30 September 2021. If this threshold is not achieved by Access Bio within the timeframe, Access Bio is obliged to make a payment for that number of units short of two million and Access Bio's exclusive rights under the agreement in the United States, Canada and Mexico automatically become non-exclusive. If the sales threshold is achieved, Access Bio's exclusive rights in the United States, Canada and Mexico will be automatically extended until 30 September 2022 with the same obligations and threshold as for the first year. The agreement will automatically renew for subsequent one year periods, provided that Access Bio continues to meet the minimum sales threshold in each year. As previously announced

to the market, Atomo is currently undertaking a scale up of its production capacity, with the increased capacity sufficient for Atomo to meet its volume obligations under the agreement. In consideration for supplying the Galileo cassettes to Access Bio, Atomo will receive a percentage of the gross revenue from all sales of the Products.

Access Bio's newly developed blood-based IgG/IgM diagnostic test detects antibodies produced in response to infection by COVID-19. Access Bio's standard test kit format received an Emergency Use Authorisation[1] (**EUA**) by the US Food & Drug Administration (**FDA**) on 24 July 2020. Access Bio's standard IgG/IgM COVID-19 rapid test uses a separate lancet to generate a blood sample and a separate manual pipette to collect and deliver blood to the test strip, unlike the Products that utilise Atomo's RDT device, where these steps are integrated. The test strip used in the multi component standard test is identical to the test strip being used in the Products. Atomo and Access Bio are working together to complete the Product dossier required to make a submission later this quarter to the FDA for EUA for the Products[2]. Corresponding regulatory submissions are also intended to be made in Canada and Mexico in the fourth quarter of 2020. These regulatory submissions will be for professional use of the Products, with regulatory submissions for the self-test variant anticipated at a later date.

Atomo considers that, if Access Bio is successful in obtaining regulatory approval in the exclusive markets of United States, Canada and Mexico, the potential revenue and earnings generated will be material.

Atomo co-founder and CEO John Kelly said, *"This is an exciting development for Atomo, and we are proud to be partnering with Access Bio on this project. Access Bio is a leading manufacturer in rapid diagnostics, with strong ties to US markets and as a long-standing trusted partner of Atomo having existing partnerships for HIV and Hepatitis C, is a natural fit for the next phase of our expansion in the COVID-19 market. Our companies believe that blood-based rapid diagnostic testing is an essential component of the global fight against COVID-19. Given the increasing urgency of the situation in the US, we are delighted to be able to play our part in attempting to defeat this pandemic."*

[1] https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas#individual-serological

[2] https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#sarscov2antibody

According to the US Centres for Disease Control and Prevention (CDC), total cases of COVID-19 in the US are currently 4,225,687, with deaths from the virus now totalling 146,546[3].

For more information, please contact:

Jane Lowe
IR Department
jane.lowe@irdepartment.com.au
Phone: +61 411 117 774

John Kelly
Atomo Diagnostics
john.kelly@atomodiagnostics.com

This announcement was authorised by John Kelly, Managing Director.

About Atomo

Atomo is a world leader in medical device design and development, headquartered in Sydney, Australia. The company specializes in creating integrated rapid diagnostic test (**RDT**) platforms for blood-based testing. The recipient of multiple international awards for innovation, Atomo's all-in-one handheld devices make it easy to test and screen for a range of infectious diseases and chronic conditions. Its patented devices simplify testing procedures and enhance usability for professional users and untrained self-testers. As well as commercializing products in its own brand, Atomo provides OEM product development services to specialist diagnostic companies worldwide. The company manufactures the only HIV self-test to have been approved by the Australian Therapeutic Goods Administration (TGA) for use in Australia. See more at www.atomodiagnostics.com

About Access Bio

Headquartered in Somerset, New Jersey, and listed on the Korean Stock Exchange (KOSDAQ: 950130), Access Bio is a specialist biotechnology company dedicated to the prevention and early diagnosis of infectious diseases through research, development, and manufacturing of in vitro rapid diagnostic tests, biosensor, and molecular diagnostic products.

With established manufacturing facilities in the USA, South Korea and Ethiopia, Access Bio and its subsidiaries manufacture more than 120 million rapid diagnostic tests annually for the detection of a range of diseases, including malaria, dengue, HIV and now COVID-19.

See more at www.accessbio.net

[3] Source: US Centres for Disease Control and Prevention: https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/cases-in-us.html