



ASX Announcement

7 December 2020

Atomo Provides Update on its HIV Rapid Test Business

SYDNEY Australia Monday, 7 December 2020: Atomo Diagnostics Limited (ASX: AT1) (**Atomo**) provides a trading update for its HIV rapid diagnostic test (RDT) business.

Highlights:

- Atomo signs agreement with PrEP Health Pty Ltd for distribution of the *Atomo HIV Self-Test* via its online PrEP subscription service in Australia.
- *Atomo HIV Self-Test* demonstrates excellent usability in independent evaluation, with 100% of untrained, first-time self-test users judging it 'easy to use'.
- International availability of Atomo's HIV self-test products continues to expand, with products supplied in recent months to Australia, Germany, UK, Vietnam, Taiwan, South Africa, and a number of other African countries.
- Following recent TGA approval, a commercial quantity of *AtomoRapid™ HIV (1&2)* professional use tests has been manufactured to support product launch in Australia in early CY2021.
- Atomo's South African HIV Operations facility now fully operational following certification by the British Standards Institution (BSI), the Australian Therapeutic Goods Administration (TGA), and the World Health Organisation (WHO).

Agreement with PrEP Health for supply of the *Atomo HIV Self-Test* in Australia

Atomo has this week signed an agreement with PrEP Health Pty Limited (PrEP Health) to exclusively supply the *Atomo HIV Self-Test* to PrEP users in Australia via its online subscription service.

Pre-Exposure Prophylaxis (PrEP) is a daily course of antiretroviral drugs (ARVs) taken by at-risk people to protect themselves from HIV infection and is known to be extremely effective at preventing HIV when taken with high adherence daily or on-demand.¹ The use of PrEP requires regular HIV testing to ensure efficacy. Adoption of the *Atomo HIV Self-Test* significantly improves convenience related to this process.

The agreement sees PrEP Health commit to purchase not less than 10,000 HIV tests from Atomo during CY2021 for deployment in Australia. The parties have also expressed interest in expanding this arrangement to international markets, with commercial discussions ongoing.

***Atomo HIV Self-Test* demonstrates best-in-class usability in independent evaluation**

In an independent evaluation carried out in Johannesburg, South Africa, during October and November 2020, Atomo's HIV self-test product demonstrated exceptional usability and was confirmed as "an easy to use, safe and reliable *in vitro* diagnostic product when used by lay users."²

¹ <https://ashm.org.au/HIV/PrEP/>

² Majam, M et al. (2020) 'Assessment of Mylan HIV self-test device: Usability and performance in the hands of untrained users in Johannesburg'



The independent study, conducted by the Wits Reproductive Health and HIV Institute (WRHI) in South Africa, assessed the test for usability and performance in the hands of untrained users. The test was well performed by lay users, with 100% of participants reporting that it was easy to use. The lay users correctly interpreted the self-test result, and their results were in 100% concordance with results read by trained laboratory technician staff.

It is anticipated that the findings of this study will support the continued commercial rollout of Atomo's HIV self-tests. The data has also been shared with leading global health bodies responsible for awarding tenders for HIV self-testing.

Increase in number of countries using Atomo's HIV self-test products

Atomo's distribution partners continue to expand the number of countries where Atomo's HIV self-test products are registered and available for sale. Since July 2020, Atomo HIV self-test products have been supplied to Australia, Germany, UK, Vietnam, Taiwan, South Africa, and multiple countries throughout Africa. Moreover, product registrations are in process in many other countries in Africa, Asia, and South and Central America to support further product launches in the coming year.

Forthcoming commercial launch of *AtomoRapid™ HIV (1&2)* professional use test in Australia

Following recent approval of the *AtomoRapid™ HIV (1&2)* professional use test by the TGA (see ASX Release 10/11/20), Atomo has manufactured quantities of the product in preparation for its commercial launch in Australia in early CY2021. The product is being targeted for use in sexual health clinics, high case load general public clinics, and other community screening settings.

With the test result given in just 15 minutes, the *AtomoRapid™ HIV (1&2)* professional use test enables the patient to discover their HIV status in a single primary care visit. This significantly reduces the waiting time compared with standard, laboratory-based test processes, and offers improved convenience for the patient and the clinician. The test also aligns with the current trend in healthcare service delivery in a decentralising environment.

South African facility operational

Following successful certification by international regulators, including the British Standards Institution (BSI), the Australian TGA, and the WHO, Atomo's assembly and packing facility for HIV test products has commenced operations. The facility, located in Cape Town, South Africa, was established to fulfil increased demand for Atomo's HIV test products for professional use and self-testing.

Atomo's Managing Director, John Kelly, said, "We are very happy with the continued progress we've made during this year as we continue to introduce our HIV test products to more and more international markets. We have invested in increased capacity and we are well placed to support our international distribution partners as they offer our best-in-class HIV rapid tests throughout the world. And we are also seeing increased demand for our products in our home market of Australia, which is extremely gratifying."



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This announcement was authorised by John Kelly, Managing Director.

About Atomo

Atomo Diagnostics is a world leader in medical device design and development, based 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 AtomoRapid™ devices make it easy to test and screen for a range of infectious diseases and chronic conditions. Atomo's patented devices simplify testing procedures and enhance usability for professional users and untrained self-testers. As well as commercialising products in its own brand, Atomo provides OEM product development services to specialist diagnostic companies worldwide.

See more at www.atomodiagnostics.com.