

ASX Announcement

24th March 2025

Atomo Secures Exclusive Licence for a Novel Syphilis Test on Pascal

- The global licence gives Atomo exclusive rights to commercialise this unique rapid test
 - Atomo signs CRC-P Partner agreements with the Burnet Institute and IDE Group for development work funded through the Australian Government CRC-P Grant

SYDNEY Australia, 24 March 2025 - Atomo Diagnostics Limited (ASX:AT1 or Atomo) Atomo is pleased to announce signing an exclusive licensing agreement with the Burnet Institute for their novel rapid Syphilis test assay. This agreement with Burnet which enables Atomo to commercialise the test on its Pascal test cassette, follows on from the awarding of a \$2.44 million Government CRC-P grant for development of the product a groundbreaking rapid test for active syphilis diagnosis¹. (ASX Release date 23rd October 2024: Atomo Secures \$2.44m Industry Grant to Develop Innovative Syphilis Test).

The agreement which remains in effect until Burnet's Syphilis patent expires in 2045, sees Atomo commit to pay Burnet a royalty payment as a percentage of net revenues generated by the Products, with a lower royalty rate applied to sales in LMIC markets where pricing is typically lower. Whilst the agreed royalty's rates are commercial in confidence, Atomo confirms they are consistent with royalties that are standard for an agreement of this nature in the diagnostics industry.

There are no material conditions that need to be fulfilled before the agreement comes into full effect, however royalty payments to Burnet under the agreement will not be applicable until after the Syphilis Products have secured regulatory approvals in key markets.

To support continued development activity under the grant, Atomo has executed CRC-P Partner agreements with the Burnet Institute and with long-time partner IDE Group. The activities being undertaken by Burnet and IDE Group under these agreements are funded through the CRC-P grant and will enable Atomo to complete development of the product, to support submissions in Australia and Europe.

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¹ https://business.gov.au/grants-and-programs/cooperative-research-centres-projects-crcp-grants/crc-projects-selection-round-outcomes



The completion of a licensing agreement with Burnet to secure exclusive rights to their Syphilis rapid test asset now enables Atomo to proceed beyond the development of the Syphilis product being funded by an Australian government grant. Under this licencing agreement with Burnet, Atomo can now commence commercial activities related to arrangements to support market entry and distribution for the product in key markets including the US and Europe where Syphilis continues to be an emerging public health challenge, with WHO estimating that 8 million acquiring Syphilis in 2022².

A recent report by the Kirby Institute indicated that rates of syphilis diagnoses in Australia have tripled over the last decade³.

This unique test, designed for both point-of-care professional use and at-home self-testing, combines Atomo's proven integrated Pascal cassette that works with a small fingerpick blood sample and a unique syphilis antibody rapid test assay developed by the Burnet Institute. Unlike current rapid Syphilis tests in the market, the test seeks to distinguish active Syphilis infections from previously treated cases, and in doing so provides improved clinical specificity in rapid test settings. Commercialisation in Pascal also improves ease of use and reliability, making the test suited for self-test deployment via pharmacy retail channels and for public health procurement models leveraging channels for at-home HIV testing.

Atomo's CEO John Kelly said "We are pleased to have now completed the CRC-P Partners agreements with both Burnet and IDE Group to support continued development of the Atomo Pascal Syphilis test. Partnering with Burnet through this exclusive global licence to support commercialisation allows us to leverage off our existing HIV test production and distribution capabilities and reflects the natural fit between the two clinical indications and the need to often test for both in sexual health screening."

Mr Kelly added, "Being able to utilise our certified low cost South African facility for production, and established sales channels in both developed healthcare markets and into Global Health is invaluable in the commercialisation of this very promising product". Atomo's HIV test is currently the only home-use test approved for supply in Australia to partners such as Blooms the Chemist and is a leading test in the UK consumer market, available at Boots Pharmacies and Tesco Supermarkets.

² https://www.who.int/news-room/fact-sheets/detail/syphilis

https://www.kirby.unsw.edu.au/research/reports/asr2023



Burnet is an Australian-based medical research institute and an accredited international non-government organisation. They undertake life-changing research and deliver health programs to ensure a better, fairer, healthier world. The Burnet Diagnostics Initiative is focussed on translating diagnostics research into practical solutions for global health problems that meet industry standards.

Director of Commercialisation and Research Translation and Director for the Burnet Diagnostics Initiative, Jennifer Barnes, said "Our partnership with Atomo has been aligned from the start, ensuring we developed a high performing innovative rapid Syphilis test that meets the requirements of manufacturers, regulators, health care providers and most importantly the patients who need it most".

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This announcement was authorised by the Managing Director & CEO on behalf of the Board.

About Atomo

Atomo is an Australian headquartered medical device company supplying unique, integrated rapid diagnostic test (RDT) devices to the global diagnostic market.

Atomo's unique patented devices simplify testing procedures, enhance usability and improve reliability across rapid point-of-care (POC) and at-home testing applications. The Company has successfully commercialised a number of products across international markets and has supply agreements in place for testing applications targeting infectious diseases including HIV, COVID-19, viral vs bacterial differentiation, as well as the early detection of pregnancy.

See more at www.atomodiagnostics.com