



## ASX Announcement

January 18<sup>th</sup> 2023

**Press Release: Atomo and NG Biotech sign new commercialisation agreement to expand the launch of a unique blood based rapid pregnancy test in key global markets**

- **Atomo secures exclusive distribution for a number of key markets - Australia & New Zealand, Canada and the US<sup>1</sup>.**
- **NG Biotech continues to manage the distribution in other markets**

SYDNEY, Australia 18 January 2023 - Atomo Diagnostics Limited (ASX:AT1) (**Atomo or the Company**) is pleased to announce the signing of a new agreement with its long-term partner NG Biotech SAS (**NG Biotech**), covering the manufacture and distribution of rapid blood-based pregnancy tests for professional use and at-home self-test use in key global markets.

The rapid test product combines a highly sensitive hCG test assay manufactured by NG Biotech and Atomo's integrated Pascal blood test device. It is acknowledged that detectable hCG levels typically build up quicker in blood than in urine, making the test potentially suited to early detection of pregnancy<sup>2</sup>.

Under the new agreement, Atomo will continue to supply NG Biotech with assembled Pascal devices and grant an exclusive licence for NG Biotech to utilise in the manufacture of finished rapid pregnancy tests for both professional use and at-home self-testing. The agreement, which has an initial period of five years and automatically renews for a further five years unless terminated by either party, sees Atomo retain ownership of all IP related to its Pascal device and NG Biotech retain ownership of all IP related to its rapid hCG test strip.

As noted in Atomo's most recent quarterly activity report, NG Biotech reordered Pascal cassettes to support the launch of its products, both of which are CE Marked in Europe and marketed by NG Biotech under their own brand. NG Biotech also recently purchased an initial quantity of Pascal cassettes to support product launch in Brazil.

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<sup>1</sup> Upon approval by Atomo of the proposed work plan and budget to be put forward by NG Biotech during Q3 FY23, Atomo will have exclusive rights to the US market.

<sup>2</sup> <https://americanpregnancy.org/getting-pregnant/understanding-pregnancy-tests/#:~:text=Advantages%20of%20having%20a%20blood%20test%20done%3A%201,healthcare%20provider%20in%20tracking%20certain%20problems%20in%20pregnancy%29>



Under the agreement Atomo has secured exclusive distribution rights for both professional and self-test versions of the product in Australia, New Zealand, Canada and the United States, and can purchase finished tests from NG Biotech for sale in these markets. Atomo will prioritise registration activities in Australia and New Zealand as product sponsor of Atomo branded versions of the test.

Under the agreement, Atomo and NG Biotech will also work together during Q3 FY23 to finalise planning and associated costs related to securing US market regulatory approvals from the US Food & Drug Administration (FDA) for US market opportunities, including seeking over-the-counter (OTC) home use approval. If Atomo approves NG Biotech's proposed work plan and costs for US regulatory approval, which will be shared by the parties, then the United States is included in the exclusive distribution territory for finished tests under the agreement.

Although the Company is unable to quantify the revenue impact at this stage, the new agreement is considered to be strategically material as the Company seeks to grow its global footprint, expand its rapid test portfolio beyond infectious diseases and leverage its opportunities in the US market.

Atomo's CEO John Kelly said "we are delighted to have been able to secure a long-term strategic partnership with NG Biotech for blood-based pregnancy testing. We have been investing in US market entry for the company and feel that these products represent a valuable commercial opportunity for us, with pregnancy testing being one of the largest established self-test categories, and with blood testing already utilised in the US in emergency settings to rule out pregnancy on admittance". Mr Kelly added, "in taking the lead in a number of key markets where we have commercial infrastructure, this agreement frees NG Biotech up to prioritise efforts in Europe and Brazil first and foremost and expand into other markets being targeted by them in the coming year".

"NG Biotech's professional use and self-test products have already secured CE Mark for sale in Europe, so we are confident in their performance and have received strong interest from potential channel partners in the US with earlier detection of pregnancy seen as a real competitive advantage when compared with more common urine rapid tests".

Atomo believes that the unique ease of use and reliability of its Pascal cassette for blood testing increases the potential for Atomo to be successful in securing approvals that enable entry into key growing CLIA-waived professional use settings and for supply over the counter and online.



For more information, please contact:

John Kelly  
Atomo Diagnostics  
[john.kelly@atomodiagnostics.com](mailto:john.kelly@atomodiagnostics.com)  
Phone: +61 401 922 279

*This announcement was authorised by the Managing Director & CEO.*

### **About Atomo**

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

Atomo's unique patented devices simplify testing procedures, reduce errors and improve 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 and pregnancy.

See more at [www.atomodiagnostics.com](http://www.atomodiagnostics.com)