

Nexsen launches clinical trial for GBS Rapid Sensor

A major milestone with this trial representing clinical validation of our next-generation diagnostic platform and potentially enables early market penetration as early as 2H CY26.

Investor Highlights:

- **Clinical trial commencement** for the GBS Rapid Sensor marks a pivotal milestone for Nexsen and its research partner, RMIT University, positioning the Company at the forefront of maternal diagnostic innovations.
- **Expectant mothers are being enrolled and tested** at the labour wards of the Northern Hospital, Epping in Victoria, demonstrating operational readiness and health sector adoption.
- **The clinical trial is being overseen by Prof. Lisa Hui**, an internationally renowned authority in maternal-fetal medicine whose oversight further underscores the program's clinical credibility and significance.
- **Nexsen is executing a robust strategy** for regulatory approvals, scaled manufacturing, and rapid market uptake across international markets.
- **Next-generation diagnostics platform** being validated in clinical trial, setting the stage for additional diagnostic tools and future commercial deployment of our product suite.
- **Trial data could support potential early market penetration as early as 2H CY26**, with various international markets being explored in addition to US FDA submission and sales.
- **Nexsen owns the StrepSure® trademark**,¹ reinforcing its commitment to proprietary branding and market leadership for the GBS Rapid Sensor product in maternal diagnostics.
- **A significant market opportunity with 132 million births per year**, and an estimated one in five pregnant women having GBS.



Above: StrepSure® Investigational Devices¹

Nexsen Limited (ASX:NXN) (Nexsen or the Company), a nano-biotechnology company developing an innovative point-of-care diagnostic platform, today announces the commencement of its clinical trial for the GBS Rapid Sensor, to be marketed as StrepSure®.¹ Expectant mothers are being enrolled and tested in the labour wards at Northern Hospital, Epping.

Nexsen's Managing Director, Mark Muzzin, commented:

"The successful completion of this trial will validate Nexsen's commercialisation strategy for the GBS Rapid Sensor, which will be marketed as StrepSure® upon launch. We are advancing our regulatory pathway, scaled production planning and global commercial rollout of our flagship diagnostic technology.

"Today marks a significant milestone for Nexsen and our partnership with RMIT University, as we initiate the first clinical trial of a diagnostic device developed using Nexsen's proprietary biosensor platform. This progress highlights our growing readiness to deliver next-generation diagnostic tools to the healthcare market at scale.

"If proven in clinical trials, StrepSure® has the ambition and potential to replace the current standard of care for screening Group B Streptococcus in expectant mothers, enabling timely intervention and substantially improving the health and wellbeing of mothers and infants."

GBS Rapid Sensor – a significant innovation in point-of-care diagnostics

The GBS Rapid Sensor is a rapid, lab-grade diagnostic device for the detection of Group B Streptococcus bacteria (GBS) in expectant mothers. GBS in the rectum or vagina of a mother at birth can result in a transfer of GBS to newborns, which is a major cause of death or serious illness in infants, as well as contributing to still and pre-term births.

Utilising Nexsen's innovative nano-biotechnology, the StrepSure® device enables real time, point of care testing, both of which are important in identifying pathogenic bacteria in expectant mothers on the day of labour.

This technology provides a fast, accurate, and accessible alternative to conventional lab-based diagnostics, allowing clinicians to make immediate, informed decisions on antibiotic use and clinical management.

This innovation represents a major step forward in maternal health, with the potential to transform the standard of care for mothers and newborns globally. Globally, there are 132 million births per year,² with an estimated one in five pregnant women having GBS.³

Clinical Trial overseen by an expert in maternal-fetal medicine at a leading hospital

The clinical trial is being led by Professor Lisa Hui as the principal investigator. Professor Hui is an internationally recognised expert in maternal-fetal medicine and practices at The Northern Hospital and the Mercy Hospital for Women, Victoria.

Commenting on the trial commencement, Prof. Hui said:

"We're excited to commence this clinical trial in the labour wards at Northern Health, marking an important step toward improving care for mothers and babies. Current GBS screening is forced to be undertaken weeks before labour because it relies on time-consuming pathology testing, yet GBS status can change by the time a woman gives birth.

"The Nexsen Rapid GBS Sensor is designed to support accurate, point-of-care testing during labour, with the potential to make GBS detection more precise, optimise antibiotic use, shorten hospitalisation, and deliver savings for the Australian healthcare system.

"So far, we've found the device simple to use and well-suited to the workflow of busy labour wards. It's rewarding to see this Australian innovation evaluated in a real clinical setting, and we look forward to seeing the full outcomes. A technology like this could be adopted across maternity hospitals, improving efficiency and outcomes nationwide."

The Northern Hospital Epping, operated by Northern Health is a leading public hospital in Victoria.

The trial has been registered with the Australia and New Zealand Clinical Trials Register (ANZCTR), and approved by the Royal Children's Hospital Melbourne Human Research Ethics Committee.

An initial 1,000 investigational devices have been manufactured in an ISO 13485 facility under the guidance of Nexsen's team and have now been delivered to the clinical trial team.

-ENDS-

ASX release authorised by the Board of Directors.

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Footnotes:

1 StrepSure® is a registered trademark owned by Nexsen Limited. StrepSure® is the intended trade name for the GBS Rapid Sensor being developed by the Company. StrepSure® is an investigational device that is yet to be approved for clinical use in Australia or any other jurisdiction.

2 United Nations (UN), World Fertility Report 2024

3 World Health Organisation, Group B Streptococcus infection causes an estimated 150,000 preventable stillbirths and infant deaths every year, 5 November 2017

About Nexsen Limited (ASX: NXN)

Nexsen is a nano-biotechnology company developing a next-generation biosensing platform that combines ultra-bright nanoparticles, high-affinity bioreceptors, and modular lateral flow architecture to deliver lab-quality diagnostics in a low-cost, user-friendly format. Nexsen's focus is on applications of its platform technology where there is a significant unmet need in a globally significant market.

Nexsen's lead product is the GBS Rapid Sensor, a rapid, point of care diagnostic tool for the detection of Group B Streptococcus in expectant mothers. Other products in development target various applications across human health, ag-tech, and biosecurity.

About Professor Lisa Hui

Professor Lisa Hui (MBBS, PhD, FRANZCOG, CMFM) is an internationally recognised leader in maternal-fetal medicine and reproductive epidemiology. She is a Dame Kate Campbell Fellow in the Department of Obstetrics and Gynaecology at the University of Melbourne and a recipient of the prestigious Norman Beischer Clinical Research Fellowship for her pioneering work to prevent infections transmitted from mothers to babies.

Professor Hui leads the Reproductive Epidemiology Group at the Murdoch Children's Research Institute, Australia's largest child health research institute, ranked top three globally for research quality and impact, and based at The Royal Children's Hospital in Melbourne. Clinically, she practices as a Maternal-Fetal Medicine Specialist at The Northern Hospital and the Mercy Hospital for Women, Victoria.

She is the Principal Investigator for the Nexsen Rapid GBS Sensor clinical trial, contributing her extensive expertise in maternal-child health to advance innovations that improve outcomes for mothers and newborns.

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