

Nexsen accelerates global rollout for StrepSure®

Nexsen Limited (ASX:NXN) (“Nexsen” or the “Company”) provides an update on the execution of its global rollout strategy for StrepSure®, with a defined pathway toward U.S. regulatory submission and early market entry initiatives underway across Asia-Pacific and emerging markets. Clinical, regulatory, manufacturing and commercial workstreams are progressing in parallel, positioning the Company to deliver a consistent pipeline of milestones over the coming months as it advances toward initial commercialisation.

Investor Highlights:

- Defined U.S. regulatory pathway via 510(k), supported by positive pre-submission engagement with the U.S. Food and Drug Administration
- Clinical strategy proactively developed incorporating both U.S. and Australian data, with FDA concurrence
- Targeting FDA submission in Q4 2026, with execution activities already underway
- Parallel strategy to enable earlier market entry in Asia-Pacific and emerging markets through local validation and registration pathways
- Quality Management System (QMS) progressing as planned, with two audits scheduled in Q2 2026 and ISO 13485 certification anticipated in early Q3 2026, including subsequent expansion to MDSAP
- Multiple near-term operational, regulatory, and commercial milestones expected over the coming months
- Early work commenced on reimbursement and payer strategies across multiple jurisdictions, including the U.S., ensuring proactive alignment with payers from the outset

Managing Director, Mark Muzzin, commented:

“Group B Streptococcus is one of the most consequential unmet clinical needs in maternal and neonatal health globally. It is a leading cause of serious neonatal injury or death. The current standard of care relies on slow lab-dependent testing, depriving clinicians of key information when they need it most. Our GBS Rapid Sensor, StrepSure®, is designed to change that.

“With our FDA regulatory pathway now confirmed this month, we are excited to unveil our global roll-out strategy, which has been structured to accelerate clinical adoption in key markets and generate opportunities for early revenue as we advance towards our FDA clearance.”

StrepSure® Rollout Strategy

Nexsen is executing a structured global rollout strategy for StrepSure®, designed to enable early market entry across select regions while progressing toward U.S. regulatory approval. The strategy prioritises markets with clear regulatory pathways, strong clinical networks and the ability to generate early validation and commercial traction. This staged approach allows Nexsen to initiate commercial activities, build real-world data and scale distribution ahead of, and alongside, its primary U.S. market entry.

United States

StrepSure® is advancing toward FDA clearance via the 510(k) pathway, following constructive pre-submission engagement confirming alignment on regulatory strategy, intended use, and analytical and clinical validation approach.

The Company had proactively developed its clinical strategy in advance of formal FDA engagement, establishing links with multiple reputable U.S hospitals and an experienced contract research organisation (CRO) to support a robust clinical program.

Clinical data collection is currently underway at Northern Health in Melbourne, Australia. In the recent Q-Sub meeting, the FDA confirmed agreement with Nexsen's proposal to include data from Australia and two U.S. sites.

Contracts for U.S. site onboarding and CRO management are anticipated imminently. These pre-emptive activities provide Nexsen with clear visibility over the remaining steps required to progress toward FDA submission, targeted for late Q4 2026.

Hong Kong

Hong Kong is being established as Nexsen's initial commercial entry point.

The rollout strategy involves local clinical validation through hospital partnerships, followed by early adoption within the healthcare system. These activities are expected to support initial revenue generation and provide real-world validation of StrepSure® in a clinical setting.

Hong Kong also serves as a gateway into China and broader North Asia markets, supporting subsequent regional expansion.

Malaysia & India

Similar to Hong Kong, Nexsen is advancing plans for local clinical validation of StrepSure® in Malaysia and India to support future regulatory registration and market entry.

- In Malaysia, a substantial partnership is emerging to support local clinical validation activities and expansion of Nexsen's platform into additional disease indications. An identified contract manufacturer is already in place, providing a pathway toward manufacturing scale-up.
- In India, the Company is progressing engagement with a contract manufacturing organisation expected to support local regulatory approvals, large-scale manufacturing, and potential market access and distribution pathways, while proactively considering product distribution and reimbursement pathways.

Emerging Markets

Following recent engagement in Africa, Nexsen has commenced discussions with non-government funding institutions (NFIs) and global health organisations to support clinical validation and deployment. The strategy is centred on aligning with public health programs and institutional partners to enable adoption at scale.

These markets represent a significant long-term opportunity, driven by high disease burden and demand for accessible, point-of-care testing.

Scaled Global Manufacturing & Quality Management System

Nexsen has established a clear manufacturing and quality pathway to support initial commercial supply and long-term global scale, meeting compliance requirements before commercial sales.

Establishing a certified Quality Management System (QMS) is a key step in this process. Nexsen has implemented its QMS, with external audits scheduled, Q2 2026, followed by expansion to MDSAP. This underpins our regulatory compliance and the ability to supply devices commercially across multiple jurisdictions.

The Company's facility, at the RMIT Sir Ian Potter Nanobiosensing Facility, will support initial production and early demand, with ISO 13485 certification underway, expected in early Q3 2026, enabling initial local manufacturing of approximately 1 million devices per annum to enable commercial supply.

In parallel, Nexsen has established its Hong Kong entity, Nexsen Hong Kong Limited, which is planned to become the Company's long-term global manufacturing and distribution hub. This hub is intended to support large-scale production, regional distribution and global supply across all current and future diagnostic products.

Hong Kong offers a uniquely supportive environment for Nexsen's next phase of growth. Hong Kong is actively positioning itself as a regional life-sciences and health-tech hub, with policy and infrastructure spanning basic research, clinical translation and advanced manufacturing. Nexsen's existing relationships with clinicians across public hospitals, private providers and their associated research networks mean that our Hong Kong manufacturing footprint will be immediately anchored in real clinical demand, rather than operating as a standalone industrial site. These collaborations create clear pathways for piloting GBS and renal biomarker LFIA tests in maternity, neonatal, renal and critical care settings across the territory and the wider Greater Bay Area.

With clinicians being embedded in local and regional professional societies, Nexsen can leverage their networks to design multi-site implementation studies, gather real-world performance data, and iterate products based on direct user feedback. The presence of an on-shore manufacturing facility in Hong Kong further reassures clinical partners regarding supply security, responsiveness to configuration requests, and alignment with local quality and regulatory expectations.

Locating LFIA manufacturing in Hong Kong positions Nexsen at the gateway to the Greater Bay Area and major global markets. Preferential pathways for Hong Kong-developed medical technologies into designated Mainland hospitals, coupled with Hong Kong's free-port status and world-class logistics, allow Nexsen to treat Hong Kong as both a test bed and a launch pad.

Near-Term Catalysts

Key execution activities over the coming months include:

1. Activation of U.S. clinical sites and progression of local trials
2. Continued clinical data generation in Australia

3. Advancement of Asia-Pacific clinical validation activities
4. Completion of QMS audits scheduled Q2 2026
5. Completion of ISO 13485 certification anticipated early Q3 2026
6. Ongoing development of early market entry initiatives across multiple regions

These parallel activities position the Company to deliver a consistent cadence of operational, regulatory, and commercial catalysts over the coming months.

Future Outlook

StrepSure® represents the first commercial application of Nexsen's diagnostic platform, with successful rollout expected to validate the Company's ability to develop and commercialise rapid, point-of-care diagnostics at scale.

This execution pathway supports expansion into additional indications already in development, including neonatal diagnostics, bovine mastitis and biosecurity applications, each targeting large, underserved markets reliant on slow or fragmented testing.

With clinical, regulatory and commercial workstreams progressing across multiple regions, Nexsen is positioned to deliver a steady pipeline of milestones over the next 6-12 months as it advances toward initial commercialisation and broader platform deployment.

-ENDS-

ASX release authorised by the Board of Directors.

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About StrepSure®

StrepSure® is a rapid lateral flow point-of-care test for the detection of Group B Streptococcus (GBS) in pregnant women. GBS affects an estimated 18% of pregnant women globally and, if undetected and untreated, can lead to serious neonatal complications including sepsis, pneumonia and meningitis.

Current testing relies on pathology labs, with results taking days, making it unsuitable for use during labour when immediate treatment decisions are required. StrepSure® delivers results in approximately 20-30 minutes at the point of care, enabling real-time clinical decision-making without the need for laboratory equipment.

The global addressable market is approximately 132 million births annually.

StrepSure® is currently an investigational device and has not yet received regulatory approval for clinical use in any jurisdiction.

About Nexsen Limited (ASX: NXN)

Nexsen is developing a suite of rapid point-of-care diagnostics designed to deliver lab-grade results for conditions that have traditionally depended on delayed laboratory testing. The company is focused on areas of significant unmet clinical need, where faster diagnosis can improve patient outcomes and reduce pressure on healthcare systems.

Nexsen's lead diagnostic is the GBS Rapid Sensor, a rapid point-of-care diagnostic for detecting Group B Streptococcus, addressing a critical unmet need in maternal health.

The Company is also developing rapid kidney function diagnostics for Acute Kidney Injury and Chronic Kidney Disease, two conditions that affect more than 850 million people globally and remain underserved by slow, lab-based diagnostics.

With further diagnostics in development across human health, ag-tech and biosecurity, Nexsen aims to become a global leader in rapid point-of-care diagnostics, delivering on its mission to ensure every person benefits from a Nexsen test at some point in their life.

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