Nexsen accelerates US Diagnostics Market Entry

Advancement of US FDA regulatory preparations with the appointment of leading medical device, diagnostics, and biologics Clinical Research Organisation and advisory firm.

Investor Highlights:

- **Appointment of MCRA** to accelerate US market entry for the GBS Rapid Sensor and Kidney Function Diagnostics
- **First US FDA engagement planned** for early 2026 for the GBS Rapid Sensor, a point of care test for Group B Streptococcus in expectant mothers on the day of labour in minutes
- **The GBS Rapid Sensor addresses a critical unmet need** with 132 million births per year globally
- **Kidney function diagnostics development is well underway**, with MCRA to advise on regulatory strategy and optimisation of activities towards first regulatory approvals
- **Market for kidney function diagnostics is significant,** with Chronic Kidney Disease affecting approximately 700 million people globally, and with Acute Kidney Injury being present in 7% of all hospital admissions and 30% of all ICU admissions globally

Nexsen Limited (**ASX: NXN**) (**Nexsen** or the **Company**), a nano-biotechnology company developing an innovative point-of-care diagnostic platform, is pleased to announce the acceleration of its US market entry for its GBS Rapid Sensor and the Kidney Function Diagnostics, with the appointment of an expert consultant advising the Company on its US FDA regulatory pathway.

Nexsen's Managing Director, Mark Muzzin, commented:

> "The appointment of MCRA is a strategic accelerator for Nexsen as we advance towards US regulatory clearance and commercial entry. Their proven track record across FDA submissions and market access for breakthrough diagnostics will be instrumental as we drive the GBS Rapid Sensor and Kidney Function Diagnostics toward first approvals and early market penetration."
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> "With our GBS Rapid Sensor clinical data now being collected under the guidance of Prof. Lisa Hui, and a clear regulatory roadmap being developed, we are building strong momentum toward positioning Nexsen as a global leader in rapid, point-of-care diagnostic technology. We are working towards an initial international market access and early sales as soon as the second half of 2026 for our GBS Rapid Sensor."

Acceleration of market entry in the US and other markets

MCRA will provide strategic regulatory and clinical guidance to support Nexsen's planned US FDA submissions and commercialisation programs. The engagement will include developing a comprehensive FDA regulatory strategy, pre-submission planning, and coordinating potential early interaction with the US FDA to facilitate an efficient path to market.

In parallel with regulatory acceleration, Nexsen is advancing commercial-readiness initiatives to bring the GBS Rapid Sensor to market in the second half of 2026. The Company is targeting early sales in selected international jurisdictions ahead of full US approval.

MCRA's commercial and reimbursement advisory divisions will support Nexsen in evaluating pricing, reimbursement and distribution strategies to maximise first-mover advantage across maternal health markets. This will also inform the broader rollout of Nexsen's Kidney Function Diagnostics suite, which targets acute and chronic kidney disease applications across both at-home and hospital environments.

Commenting on their engagement by Nexsen, Director of IVD Regulatory Affairs, Dr Natasha Griffin of MCRA said:

> "MCRA is honoured to support Nexsen's development of their GBS Rapid Sensor and to play a role in the future of their diagnostic pipeline. We look forward to the continued partnership – exciting times ahead."

Clinical trials for GBS Rapid Sensor are underway

The collaboration follows the commencement of Nexsen's first clinical trial for the GBS Rapid Sensor, led by Professor Lisa Hui, a globally recognised authority in maternal-fetal medicine. Clinical data generated from this program will underpin FDA submission and broader international regulatory filings.

Utilising Nexsen's innovative nano-biotechnology, the GBS Rapid Sensor will enable real-time, point-of-care testing, both of which are important in identifying Group B Streptococcus (**GBS**) bacteria in expectant mothers on the day of labour, in minutes, not days.

The GBS Rapid Sensor addresses a key unmet need and a globally significant market opportunity. Global estimates indicate 132 million births per year and an incidence rate of one in five pregnant women carrying GBS.[1]

Kidney function diagnostic development advances

Nexsen is also developing rapid, point-of-care diagnostics for the screening, detection, and ongoing monitoring of various subsets of Chronic Kidney Disease (CKD) and Acute Kidney Injury (AKI).

A rapid and accurate diagnosis of a patient's kidney status is critical – whether it be in the ambulance, the Intensive Care Unit, or at home.

CKD is estimated to affect approximately 700 million people globally, with a prevalence of 11% to 14% in countries such as the United States, Australia, the United Kingdom, and India.[2] AKI is particularly prevalent in hospitalised patients, with estimates at 7% of all hospital admissions and 30% of ICU admissions globally. In context, there are approximately 5.7 million ICU admissions in the US annually.[3]

The availability of a rapid, cost-effective, point-of-care diagnostic test for these patients would enable more frequent monitoring of kidney health and facilitate earlier identification and initiation of treatment.

With MCRA's guidance, Nexsen aims to optimise and accelerate its regulatory and commercialisation strategy, exploring the potential for accelerated regulatory approval pathways for these diagnostic tools in the US.

Additional Disclosure

MCRA's engagement has been effected by way of Nexsen's execution of a Master Consulting Services Agreement with various members of the IQVIA group (a leading global provider of clinical research services, commercial insights and healthcare intelligence), of which MCRA is a member. That agreement enables Nexsen to contract with IQVIA entities for the provision of services from time to time, as set out in a specific work order relating to those services. MCRA and Nexsen have in turn entered into such a work order, which governs the basis on which MCRA will provide Nexsen with the strategic regulatory and clinical guidance services referred to above. The appointment of MCRA is on terms customary for agreements of a similar nature in this industry, with Nexsen to pay MCRA on a project basis at its standard hourly rates which the Company considers to be reasonable.

-ENDS-

ASX release authorised by the Board of Directors.

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Footnotes:

1 United Nations (UN), World Fertility Report 2024 and World Health Organisation, Group B Streptococcus infection causes an estimated 150,000 preventable stillbirths and infant deaths every year, 5 November 2017

2 Frost and Sullivan Market Report, Section 5, Nexsen Prospectus https://www.nexsen.bio/prospectus

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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 that address a significant unmet need in a globally important market.

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

About MCRA

MCRA is a leading, industry-specialised, multi-service, employee-based, integrated business that assists clients throughout the technology life cycle, from research and development through commercialisation. Our team provides services to a wide range of organisations in the healthcare industry, including start-ups, the world's leading healthcare organisations, all types of financial investors, global manufacturers, and individuals.

MCRA's core clientele consists of all arenas of medical devices, with a concentrated focus on neuro-musculoskeletal healthcare; this includes all industry sub-niches that involve orthopedic, cardiology, diagnostic imaging, sports medicine, tissue regeneration, biologics/orthobiologics/biomaterials, orthotic/prosthetic, wound care, in vitro diagnostics, and imaging/software devices.

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