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Nexsen advances kidney diagnostics program

Highlights:

- **RenalSure® targeting FDA submission in mid-2027:** Nexsen's first kidney diagnostic is advancing through development and clinical validation.
- **149 million AKI tests annually[1]:** Significant repeat-testing opportunity across the US, UK, and Australia, targeting a global diagnostics market worth US$1.03 billion in 2026, and is forecast to reach US$1.71 billion by 2033.[2]
- **Targeting a critical need in intensive care:** AKI affects 57% of ICU patients in a major international study, with demand for rapid diagnosis and repeat monitoring.
- **Complementary AKI diagnostic adds commercial potential:** Feasibility study underway with GENSPEED, leveraging established CE-IVD marked technology delivering results in approximately 15 minutes in existing applications.

Nexsen Limited (**ASX:NXN**) ("**Nexsen**" or the "**Company**") is pleased to provide an update on its kidney diagnostics program, initially targeting Acute Kidney Injury (AKI). The Company's proprietary RenalSure® bedside test is progressing towards a targeted US FDA submission in mid-2027, alongside a new feasibility study with Austrian diagnostics company GENSPEED Biotech to evaluate a complementary cartridge-based AKI test.



Figure 1: GENSPEED multiplex test chip (left) and GENSPEED analyser (right)

Targeting a significant unmet clinical need

AKI is a sudden loss of kidney function and one of the most common complications in intensive care and major surgery. An international study of 1,802 intensive care patients found that 57.3% developed AKI, with more severe AKI linked to substantially higher hospital mortality.[3] In a study of 3,101 cardiac surgery patients, 25.9% developed AKI, and in-hospital mortality was 6.2% for those with AKI compared with 0.7% for those without.[4]

Current monitoring relies heavily on serum creatinine, which may not rise until kidney injury is already established. This creates a need for faster assessment and more frequent monitoring to support clinical decisions.

The commercial opportunity is underpinned by repeat testing throughout a patient's ICU stay. Based on estimated ICU admissions and testing frequency, the addressable opportunity across the US, UK and Australia is approximately 149 million tests annually[1]. The global AKI diagnostics market is estimated at approximately US$1.03 billion in 2026, and is forecast to reach US$1.71 billion by 2033.[2]

AKI is the initial target within a much broader kidney diagnostics opportunity. Kidney disease affects an estimated 850 million people worldwide,[1] and the Company sees potential to apply the clinical and development experience gained in AKI to chronic kidney disease over time.

RenalSure®: Nexsen's proprietary bedside test

RenalSure® is Nexsen's proprietary rapid, urine-based lateral flow diagnostic, designed to assess kidney injury risk at the bedside without relying on a central laboratory. Development is progressing towards a targeted US FDA submission in mid-2027, subject to successful development and clinical validation. Nexsen's existing biobank of stored urine samples from critically ill patients is expected to support clinical validation, potentially reducing reliance on new patient recruitment and accelerating the generation of clinical evidence.

The Company has also registered the RenalSure® and KidneySure® trademarks in Australia, establishing the brands for its growing kidney diagnostics portfolio.

GENSPEED feasibility study expands commercial offering

Nexsen has commenced a feasibility study with Austrian diagnostics company GENSPEED Biotech GmbH ("GENSPEED") to evaluate a complementary cartridge-based AKI test using its established micro-ELISA technology. GENSPEED's CE-IVD marked analyser can measure up to eight markers simultaneously, delivering results in approximately 15 minutes in existing applications, with less than three minutes of hands-on time.

By leveraging an established analyser, Nexsen can focus its development efforts on the AKI assay and clinical validation, rather than developing new hardware. RenalSure® supports quick bedside testing at first contact, while the GENSPEED-based assay provides more detailed monitoring and risk assessment across hospital settings. As different hospitals have different preferences, offering both tests creates a flexible, end-to-end renal testing portfolio that can serve a wider range of hospital needs. Subject to successful feasibility results, the technology could also support future diagnostic applications across Nexsen's existing critical-care programs, including traumatic brain injury and neonatal sepsis.

Nexsen Managing Director, Mark Muzzin, commented:

"Acute Kidney Injury represents a significant opportunity for Nexsen. It's a common and serious complication in intensive care, where clinicians need timely information and kidney function can require repeated monitoring throughout a patient's stay.

"We're making good progress with RenalSure® as we work towards our targeted FDA submission in mid-2027. At the same time, the GENSPEED feasibility study gives us an opportunity to pursue a complementary test, allowing us to address different hospital testing requirements.

"Our focus is on building a kidney diagnostics portfolio that meets genuine clinical needs, with the potential to expand into further critical-care applications."

[1] Frost & Sullivan Market Report, included in the Nexsen Limited Prospectus dated 29 August 2025. AKI addressable market assumes an average ICU stay of four days and six tests a day.

[2] Grand View Research (2026), Acute Kidney Injury (AKI) Diagnostic Market Size Report, 2026–2033. Estimates cover the global category, not Nexsen's addressable share.

[3] Hoste et al. (2015), Epidemiology of acute kidney injury in critically ill patients: the multinational AKI-EPI study, *Intensive Care Medicine*, 41, 1411–1423.

[4] Strauß et al. (2025), Risk factors, outcomes, and early prediction of cardiac surgery-associated acute kidney injury: a post hoc subgroup analysis of the Epidemiology of Surgery Associated Acute Kidney Injury study, *British Journal of Anaesthesia*, doi:10.1016/j.bja.2025.08.043.

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ASX release authorised by the Board of Directors.

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About Nexsen Limited (ASX: NXN)

Nexsen is developing a growing portfolio of rapid point-of-care diagnostics for serious conditions where delays in diagnosis can affect patient outcomes and limit the ability of clinicians to make fast, informed treatment decisions. The Company's lead programmes include diagnostics for Group B Streptococcus (GBS) in maternal health and kidney function, targeting Acute Kidney Injury and Chronic Kidney Disease. Together, these programmes address significant areas of unmet clinical need across large global patient populations. Nexsen is also advancing additional diagnostic programmes across traumatic brain injury, neonatal sepsis and biosecurity, supported by a growing international research, clinical and commercial network across Australia and Asia.

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