Clear pathway defined to optimise StrepSure

Highlights:

- **Nexsen to optimise StrepSure for FDA submission; timing anticipated to move by approx. a quarter**
  Nexsen will incorporate the clinical learnings into an enhanced StrepSure before submitting to the US Food and Drug Administration (FDA). The planned enhancements are targeted improvements to the existing device rather than a fundamental redesign and are not expected to require material additional development expenditure.
- **Interim review delivers a clear pathway to strengthen StrepSure**
  The predefined review has provided valuable real-world evidence before Nexsen commits to a larger US regulatory study, allowing the Company to optimise the product at an earlier and lower-cost stage of development.
- **Strepsure development focused on signal enhancement**
  The next phase will concentrate more GBS from each sample, read the signal more clearly through quantitative electronic measurement and confirm it through stronger biological recognition.
- **Asia-Pacific strategy and wider business continue as planned**
  The revised timing relates only to StrepSure's US regulatory pathway. StrepSure continues to progress for antenatal screening and decentralised care across Asia-Pacific, supported by the GBS clinical validation work with The University of Hong Kong, while Nexsen's other programmes and commercial strategy continue as planned.
- **Broader diagnostics platform pipeline continues to progress**
  Alongside StrepSure, Nexsen is advancing diagnostics across kidney disease, traumatic brain injury, neonatal sepsis and biosecurity, supported by a growing research, clinical and commercial network across Australia and Asia.

Nexsen Limited (**ASX:NXN**) ("**Nexsen**" or the "**Company**"), an emerging leader in rapid point-of-care diagnostics, is pleased to provide an update on the ongoing clinical programme for StrepSure, its rapid lateral-flow test for Group B Streptococcus (GBS).

The StrepSure clinical study is being conducted at Northern Health in Melbourne and evaluated StrepSure in women in labour, the real-world setting in which the test is intended to be used. The study deliberately included a predefined interim review to assess early-stage performance, allowing Nexsen to refine the programme before committing to a larger US regulatory study. That review has now taken place and enrolment has been suspended in line with the study protocol. There has been no adverse safety signal or event.

Following a review of the interim data, together with ongoing scientific and regulatory assessment, the assessment of StrepSure in its current form has ceased and Nexsen has identified a targeted set of enhancements to strengthen StrepSure ahead of its US FDA submission. The review has provided Nexsen with real-world clinical evidence at a point where the product can still be optimised before substantially greater time and capital are committed to the US regulatory pathway. Based on the findings, the Company will incorporate the study learnings into an enhanced device before returning to the US pathway with a stronger product and stronger supporting evidence.

The planned enhancements are targeted improvements to the existing StrepSure platform rather than a fundamental redesign, and are not expected to require material additional development expenditure. Nexsen expects the previously targeted Q4 2026 FDA submission to move by approximately one quarter, with updated timing confirmed as the programme progresses.

Managing Director, Mark Muzzin, commented:

"We have made the decision not to submit the current configuration to the FDA and instead use what we have learned to make StrepSure stronger. Making this decision now avoids committing substantially more capital to the current configuration and reduces the risk of having to repeat clinical and regulatory work at a later, more expensive stage. We currently expect this to move the US submission by around one quarter, which we believe is the right decision before progressing to a larger regulatory programme.

Importantly, this is specific to StrepSure's US pathway. Our Asia-Pacific strategy continues, our other diagnostic programmes continue to progress, and the capabilities we are building through StrepSure have application across the broader Nexsen platform."

Clinical review sharpens the development pathway

The interim data provided clear evidence of StrepSure's ability to detect GBS in the intended clinical setting and identified clear opportunities to further strengthen performance before progressing to a larger US regulatory programme.

Importantly, the interim review also identified that GBS prevalence at the trial site was ~11%, materially below the 18% to 25%[1] prevalence seen at many US study sites. This resulted in fewer GBS-positive cases being captured through the study and it has clarified what StrepSure needs to achieve in lower-prevalence settings.

Low prevalence does not make a test perform worse. What it does is raise the bar: where GBS is less common, a test must be especially good at avoiding false positives for a positive result to be reliable. This is sometimes called the "prevalence trap". It is a recognised feature of all diagnostic testing, not something unique to StrepSure or to lateral-flow technology. The value of testing StrepSure in a real-world hospital population is that it identified this requirement before Nexsen committed to a larger US regulatory programme, while also providing relevant evidence for the lower-prevalence settings the product is intended to serve.

The Company remains confident in the underlying StrepSure technology and is now incorporating these findings into the next generation of the product. Nexsen is progressing enhancements designed to improve sensitivity, specificity and consistency, alongside broader clinical evaluation, before the integrated design is validated ahead of the US submission.

StrepSure is now being strengthened through three key development initiatives, while retaining the advantages of a rapid, portable and lower-cost lateral-flow format:

- **Sample concentration**: a magnetic-bead step that concentrates GBS from the swab sample before it reaches the test strip, increasing the signal available for detection.
- **Quantitative electronic readout**: enhanced upconversion nanoparticle (UCNP) reader technology designed to provide signal enhancement and measure weaker signals more precisely and consistently than a visual read.
- **Dual-recognition**: architecture using two independent methods to identify GBS, designed to improve sensitivity and specificity and reduce incorrect results.

Asia-Pacific strategy continues

Alongside the optimisation of the US programme, Nexsen will continue to progress StrepSure for antenatal screening and decentralised healthcare settings across Asia-Pacific, where its rapid, portable and lower-cost format is well suited to clinics, mobile health services and other settings where access to laboratory testing may be limited.

This work is already underway through Nexsen Hong Kong. The University of Hong Kong (HKU) is supporting microbiology research and clinical validation of Nexsen's GBS diagnostics, based around the Company's

Hong Kong R&D facility, and complementing its hospital partnership with IHH Healthcare's Gleneagles Hospital Hong Kong. This gives StrepSure an established clinical and research base in the region.

Broader use across these settings is also expected to build additional clinical performance data across different patient populations, strengthening the evidence base for a future US submission.

The revised timetable therefore relates specifically to StrepSure's US regulatory pathway. It does not delay the Company's broader commercial strategy or the development of Nexsen's other diagnostic programmes.

Non-Executive Director, Professor Shekhar Kumta added:

"The interim review gave us a structured opportunity to stop, look at the evidence and continue with better information. The prevalence effect is a feature of diagnostic testing and does not change the underlying science behind StrepSure.

The analysis has sharpened Nexsen's development priorities and reduced the risk of avoidable repeat development and late-stage rework. We now have a much clearer development brief for the next generation of StrepSure before progressing further."

-ENDS-

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.

[1] Clin Infect Dis. 2017 Nov 6;65(Suppl 2):S100–S111.

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