QMS Milestone Achieved to Support Regulatory and Commercial Activities

Nexsen Limited (ASX:NXN) ("Nexsen" or the "Company") provides an update on the progression of its Quality Management System (QMS), which underpins the development, clinical validation and commercialisation of its diagnostic products, including StrepSure®.

Investor Highlights:

- Successful completion of Stage 1 ISO 13485 audit conducted by BSI
- QMS confirmed as appropriately structured to support clinical validation, regulatory submissions and future commercial manufacturing
- Progression toward ISO 13485 certification and alignment with Medical Device Single Audit Program (MDSAP) requirements remain on track
- QMS forms a critical foundation for Nexsen's global regulatory and commercial rollout strategy

Managing Director, Mark Muzzin, commented:

"Establishing a robust Quality Management System is a critical step in translating diagnostic technologies from development through to clinical validation and commercialisation.

The successful completion of our Stage 1 audit confirms that our QMS is appropriately structured to support our clinical and regulatory programs, including the advancement of StrepSure® across multiple regions."

Quality Management System progression

Nexsen has successfully completed its Stage 1 ISO 13485 audit, conducted by BSI, a globally recognised certification body.

This milestone provides a critical foundation for Nexsen's planned clinical validation activities, regulatory submissions and future commercial manufacturing operations, including the advancement of StrepSure®.

The Company is progressing toward its Stage 2 certification audit, with ISO 13485 certification and alignment with MDSAP requirements remain on track.

Supporting global regulatory and commercial expansion

A certified Quality Management System is a foundational requirement for regulatory approvals and commercial supply across global markets.

Progression of Nexsen's QMS supports its ability to advance regulatory and commercial activities across multiple jurisdictions, including:

- The United States and other MDSAP-participating jurisdictions, where alignment with MDSAP requirements supports efficient regulatory inspections and multi-market access

- Australia and Asia-Pacific markets, where ISO 13485 certification underpins regulatory approval, clinical validation and early commercial deployment
- Future expansion into Europe, where ISO 13485 certification forms a foundational requirement for regulatory approval and market entry

In addition, alignment with MDSAP requirements is expected to enable Nexsen to leverage a single audit framework across multiple jurisdictions, supporting efficient global expansion and reducing regulatory complexity.

-ENDS-

ASX release authorised by the Board of Directors.

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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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