

## Business Update: FDA engagement underway & key appointment

Nexsen Limited (ASX:NXN) ("Nexsen" or the "Company") provides a business update highlighting the commencement of FDA engagement for its GBS rapid sensor, progress toward US market entry and continued strengthening of the Company's leadership and innovation credentials. Together, these developments reinforce Nexsen's delivery against its strategy and provide greater clarity around the near-term regulatory and commercial pathway.

### Investor Highlights:

- **FDA engagement commenced for entry into world's largest maternal health market**, with approximately 3.7 million births per year, following lodgement of a pre-submission for Nexsen's GBS rapid sensor
- **Pre-submission lodged ahead of schedule under the FDA-510(k) diagnostic pathway**, establishing a defined and near-term regulatory pathway toward US market entry
- **FDA feedback expected within approximately 70 days**, informing Nexsen's subsequent formal 510(k) submission with clearance based on validation data from the ongoing clinical trials
- **Commercial and financial readiness strengthened** with the appointment of an experienced Chief Financial Officer, supporting disciplined financial management and market rollout activities
- **Scientific leadership recognised**, with Chief Innovation Officer Professor Vipul Bansal awarded a Distinguished Professorship by RMIT University for his contributions to nanobiotechnology research

### Nexsen's Managing Director, Mark Muzzin, commented:

"We're pleased to announce our FDA pre-submission lodgement as we advance toward our 510(k) submission. Our strategic approach to the regulatory pathway positions Nexsen to achieve market clearance significantly faster than traditional therapeutic development, which requires multi-phase clinical trials and extended timelines. With robust clinical data from our multi-site trials and FDA feedback on our validation approach, we're well-positioned for efficient US market entry and to deliver real-world impact in diagnostics".

### FDA Pre-Submission Lodged for GBS Rapid Sensor

Nexsen has lodged a Pre-Submission with the US Food and Drug Administration (FDA) for its rapid Group B Streptococcus (GBS) point-of-care diagnostic, marking the commencement of FDA engagement for US market entry and achieved **ahead of schedule**.

The GBS Rapid Sensor provides lab-grade GBS diagnosis in minutes at the point-of-care, addressing a critical clinical need in maternal care where current testing relies on delayed laboratory results. Rapid detection of GBS supports detection at the time of labour, allowing for more timely clinical decision-making and improved outcomes.

Nexsen is advancing clinical trials across multiple hospital sites as part of its pathway toward FDA 510(k) submission. Unlike therapeutic or vaccine development, which often requires extensive multi-phase studies and lengthy regulatory timelines, the 510(k) process for medical diagnostics is far more streamlined.

To accelerate this trajectory, Nexsen has initiated a pre-submission meeting with the FDA, seeking feedback on intended use, predicate selection, and validation approach, with written guidance expected within approximately 70 days. This proactive regulatory engagement positions Nexsen to achieve market clearance in a fraction of the time required for traditional drug development, enabling faster market entry and earlier revenue potential.

Following FDA feedback, Nexsen will finalise its clinical validation program, ensuring alignment with FDA expectations ahead of a formal 510(k) submission for its US market clearance.

### **Appointment of Chief Financial Officer**

Nexsen has appointed Richard Jarvis as Chief Financial Officer, initially in a fractional capacity. Richard is the Founder of *The CFO Bridge*, that provides virtual CFO and Business Advisory services to entrepreneurial and emerging ASX listed companies. The appointment forms part of Nexsen's continued focus on building the right capabilities as the Company prepares for commercial readiness, market rollout and international expansion.

Richard is a Chartered Certified Accountant with more than 25 years of executive finance and accounting experience, including 18 years in CFO roles at ASX and dual-listed ASX-AIM companies operating across various sectors.

His experience supports Nexsen's progression toward commercial operations, capital markets engagement and international growth, as the Company continues to advance its rapid diagnostics platform toward global markets.

Richard brings substantial international experience, having operated across Australia, the UK, Asia and multiple African jurisdictions and has developed a strong global professional network. The international perspective aligns with Nexsen's strategy to pursue global regulatory pathway and future market entry, supporting the Company's ambition to become a global leader in rapid point-of-care diagnostics.

### **Recognition of Chief Innovation Officer**

Nexsen is proud to celebrate its Chief Innovation Officer, Professor Vipul Bansal, who has been awarded the prestigious title of RMIT Distinguished Professor, one of the University's highest academic honours. The recognition highlights Professor Bansal's global leadership in nanotechnology and his remarkable ability to turn groundbreaking research into innovations that deliver real-world impact across healthcare and beyond.

The award recognises Professor Bansal's exceptional contributions to nanotechnology, biosensing, and applied medical diagnostics, and reflects his global standing in the field. His leadership continues to underpin Nexsen's diagnostics platform, including the GBS rapid sensor and the Company's broader pipeline of rapid diagnostic solutions.

This recognition further reinforces the depth of scientific expertise supporting Nexsen's technology and long-term innovation strategy.

-ENDS-

ASX release authorised by the Board of Directors.

For more information, please contact:

#### Corporate Enquiries

Nexsen Limited

e: [corporate@nexsen.bio](mailto:corporate@nexsen.bio)

w: [nexsen.bio](http://nexsen.bio)

Reign Advisory

e: [NXN@reignadvisory.com](mailto:NXN@reignadvisory.com)

p: + 61 2 9174 5388

#### Media Enquiries

Jane Morgan Management

e: [info@janemorganmanagement.com.au](mailto:info@janemorganmanagement.com.au)

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### About Nexsen Limited (ASX: NXN)

Nexsen is developing a suite of rapid point-of-care diagnostics that deliver lab-grade results for conditions that have traditionally relied on delayed lab testing. The company focuses on areas of significant unmet clinical need, where faster answers 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 tests 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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