Nexsen

Quarterly Report – Q1 FY26

Investor Highlights:

- **Successful Capital Raise and ASX Listing: Nexsen raised $8 million through an IPO and listed at a premium. The Company also received an additional $0.64 million via the R&D Tax Incentive.**
- **Kidney Function Diagnostic advancements: Nexsen with our strategic research partner, RMIT University, have rapidly advanced our suite of kidney function tests, targeting a global market of approximately 700 million CKD patients and the high prevalence of AKI in ICUs.**
- **Strengthened the leadership team: The appointments of Prof. Vipul Bansal (CIO) and Dr. Sanje Mahasivam (CTO). Both bring extensive technological and commercialisation expertise.**
- **The clinical trial for the Group B Streptococcus (GBS) Rapid Sensor: Trial commenced in October 2025, enabling Nexsen to prepare an FDA 510(k) pathway submission as a quicker, more affordable way to access the US market.**

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Nexsen Limited (ASX:NXN) (**Nexsen** or the **Company**), a nano-biotechnology company developing an innovative point-of-care diagnostic platform, provides an update on its activities for the quarter ending 30 September 2025 (**Q1 FY26** or the **September Quarter**). An Appendix 4C for the quarter is enclosed. The Company notes that the quarter ended prior to Nexsen's admission to the Official List of the ASX

Nexsen Managing Director, Mark Muzzin, commented: "This quarter was a significant period for the company as we worked through the IPO process and introduced investors to the Nexsen story and the start of clinical validation of our first device, our GBS Rapid Sensor."

Nexsen achieved two key corporate milestones in October 2025; an ASX listing after raising $8 million and commencing our clinical trials for the GBS Rapid Sensor.

The IPO capital raise, combined with the $0.64 million in cash receipts from R&D Tax Incentive payments received during the quarter, provides the company with the funding needed to bring the GBS Rapid Sensor to commercialisation and to continue developing our broader suite of diagnostics targeting unmet needs in globally significant markets.

$8 million capital raising and ASX Listing

Nexsen successfully raised $8 million through its IPO completed in Q1 FY26. The raise was led by Alpine Capital with support from several major institutional investors. Additionally, Nexsen received $0.64 million during the quarter from the R&D Tax Incentive payment.

The Company was admitted to the Official List of ASX on Friday, 10 October 2025, with trading commencing on Tuesday, 14 October 2025.

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Kidney function diagnostics suite accelerating momentum

During the quarter, Nexsen and RMIT have made significant progress in the development of Nexsen's rapid, point-of-care diagnostics aimed at screening, detecting, and monitoring various forms of Chronic Kidney Disease (CKD) and Acute Kidney Injury (AKI).

The technological progress achieved through the GBS Rapid Sensor program provides a blueprint for Nexsen's broader diagnostic platform. Nexsen expects this to enable an accelerated validation and commercialisation pathway for its kidney function diagnostic suite.

A swift and precise diagnosis of a patient's kidney health is essential – whether it is in the ambulance, the Intensive Care Unit, or at home.

CKD is estimated to affect around 700 million people worldwide, with a prevalence between 11% and 14% in countries like the United States, Australia, the United Kingdom, and India.[1]

AKI is especially common in hospitalised patients, accounting for about 7% of all hospital admissions and 30% of ICU admissions globally. In context, roughly 5.7 million ICU admissions occur in the US each year.[1]

Having a quick, affordable point-of-care test for these patients would allow for more regular monitoring of kidney health and help with earlier detection and start of treatment.

Expansion of senior leadership providing exceptional scientific and commercialisation capability

During the quarter, Nexsen was pleased to finalise arrangements with Prof. Vipul Bansal and Dr Sanje Mahasivam to become senior executives of Nexsen in addition to their roles at RMIT University.

Prof. Bansal is a recognised nanotechnology expert, Fellow of the Royal Society of Chemistry, former Australian Future Fellow, with over twenty years of experience leading diagnostics and biosensor innovations. Prof. Bansal founded and heads the Sir Ian Potter Nanobiosensing Facility at RMIT University. Engaging Prof. Bansal directly as Nexsen's Chief Innovation Officer (CIO) solidifies his important and influential role within the Company.

Dr Mahasivam has had a distinguished multidisciplinary career encompassing research, innovation, product development, and commercialisation. He has led industry-scale R&D collaborations, including with Monash University and Woodside Energy, and holds multiple patents in MedTech and materials science. His leadership has facilitated the successful transition of patented concepts into commercially viable products and high-impact industrial innovations. Additionally, Dr Mahasivam was appointed by Nexsen as Chief Technology Officer (CTO), alongside his senior role at the Sir Ian Potter Nanobiosensing Facility at RMIT University.

Led by Managing Director and Nexsen founder Mark Muzzin, Prof Bansal and Dr Mahasivam bring outstanding scientific and commercialisation expertise to the executive team, boosting Nexsen's ability to convert world-class R&D into clinically and commercially proven diagnostic products.

Commencement of Clinical Trials for the GBS Rapid Sensor

The GBS Rapid Sensor is a fast, laboratory-grade diagnostic device for detecting Group B Streptococcus bacteria (GBS) in expectant mothers. GBS present in the rectum or vagina of a mother at birth can be

transmitted to newborns, which is a leading cause of death or serious illness in infants and also contributes to stillbirths and pre-term births. Nexsen's GBS Rapid Sensor clinical trial is led by Prof. Lisa Hui as the principal investigator. Prof. Hui is an internationally recognised expert in maternal-fetal medicine and practices at The Northern Hospital and the Mercy Hospital for Women, Victoria.

During the quarter, Nexsen finalised the registration of the clinical trial on the Australia and New Zealand Clinical Trials Register (ANZCTR) and completed all other required preliminary steps, enabling the start of the clinical trial in early October 2025 following Nexsen's ASX listing.

Commenting on the GBS Rapid Sensor, Prof. Lisa Hui said: "So far, we've found the device simple to use and well-suited to the workflow of busy labour wards. It's rewarding to see this Australian innovation evaluated in a real clinical setting, and we look forward to seeing the full outcomes. A technology like this could be adopted across maternity hospitals, improving efficiency and outcomes nationwide."[2]

This innovation marks a significant advance in maternal health, with the potential to improve the standard of care for mothers and newborns worldwide. Globally, there are 132 million births annually,[3] with an estimated one in five pregnant women having GBS.[4]

Nexsen is advancing the GBS Rapid Sensor through expedited routes to global markets after successful clinical validation and data collection. In the US, Nexsen will bring the GBS Rapid Sensor to market using the FDA 510(k) pathway. The FDA 510(k) process is a faster and more cost-effective option for low- to moderate-risk devices that can be considered "substantially equivalent" to a legally marketed predicate device. An FDA 510(k) approval could be secured within months of submission, compared to years for other pathways. Similar accelerated pathways are being explored in other key markets for Nexsen.

Overview of FDA 510(k) pathway

The FDA 510(k) pathway enables medical device manufacturers to gain market clearance by demonstrating their device is substantially equivalent to an existing legally marketed predicate device. It involves submitting detailed technical and performance data to the FDA for review. The process begins with preparation, including selecting a predicate device and possibly engaging the FDA through Pre-Submission meetings to clarify expectations.

The 510(k) submission is then electronically filed, followed by an initial administrative acceptance review within about 15 days. If accepted, the FDA conducts a substantive review involving technical evaluation and may request additional information from the manufacturer. This review phase typically targets a 90-day timeframe but can extend if information requests occur.

If the device is found substantially equivalent, the FDA issues a clearance letter allowing marketing in the US. The review process includes multiple communication points between the FDA and the manufacturer to address issues and clarify data. Post-clearance, manufacturers must comply with ongoing regulatory requirements related to device registration, labelling, and quality systems.

Overall, the 510(k) pathway streamlines market entry for moderate-risk medical devices by leveraging predicate comparisons, balancing timely patient access with robust regulatory oversight.

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The Nexsen GBS Rapid Sensor is well suited to the 510(k) pathway because it is designed as a moderate-risk diagnostic device with precedent predicate devices in the market, enabling demonstration of substantial equivalence without the need for a more complex Premarket Approval (PMA). This allows Nexsen to leverage established regulatory requirements and expedite market entry while assuring safety and effectiveness.

This pathway offers a balance of timely FDA review and rigorous oversight, supporting Nexsen's strategy to bring its innovative rapid GBS sensor to US clinical markets efficiently.

Review of cash flows and activities during the Quarter

Nexsen adopted a cash conservation approach to managing its cash outflows during the period leading up to its ASX Listing. As a result, Nexsen's operational cash outflows for the September quarter will be higher compared to the December quarter. Operational cash outflows in the quarter were mainly related to research and development and staff expenses. Cash inflows are primarily from the $0.64 million R&D Tax Incentive payments received in September.

The Company also received a significant amount of the IPO Offer funds by the end of the Quarter; however, these funds were held in trust for investors as required by the Corporations Act 2001 (Cth) and were not available for expenditure. The Company does not provide a comparison of its expenditure against the "use of funds" statement in the Prospectus, as required by ASX Listing Rule 4.7C.2, because the Quarter ended prior to the Company's admission to the Official List of the ASX and therefore before the funds raised under the Prospectus were spent.

Related party payments during the quarter totalled $208,000, consisting of regular remuneration to current and former directors.

Strong momentum into the new year

With the Company now listed and well-funded, Nexsen moves into the rest of the year with strong operational momentum. Key short-term priorities include continuing to gather clinical data for the GBS Rapid Sensor, quickly advancing our kidney function diagnostics, and developing our broader range of point-of-care and point-of-use diagnostic tools.

-ENDS-

ASX release authorised by the Board of Directors.

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Footnotes:

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

2 Nexsen ASX Release 21 October 2025 "Nexsen launches clinical trial for GBS Rapid Sensor"

3 United Nations (UN), World Fertility Report 2024

4 World Health Organisation, Group B Streptococcus infection causes an estimated 150,000 preventable stillbirths and infant deaths every year, 5 November 2017

About Nexsen Limited (ASX: NXN)

Nexsen is a nanobiotechnology 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 an affordable, easy-to-use format. Nexsen's focus is on applications of its platform technology where there is a considerable unmet need in a globally important market.

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

Forward Looking Statements Disclaimer

Forward looking statements are typically identified by the use of forward looking terminology such as 'aims',' believes',' expects',' may',' will',' could',' should',' seeks',' intends',' estimates',' plans',' assumes',' envisages', or the negative thereof or other words of similar meaning. Examples of such forward looking statements include, among others, statements or discussions regarding the Company's business, financial or investment strategies, regulatory and commercialisation strategies, estimates of expenditure, present or future plans or events, prospects, growth, objectives for future operations and estimates. Such forward looking statements include matters that are not historical facts and are subject to a number of risks and uncertainties, many of which are beyond the Company's control and all of which are based on the Company's current beliefs, intentions or expectations about future events. Such statements are, by their nature, subject to a number of known and unknown risks, uncertainties, assumptions and other important factors that could cause actual results, performance or achievements to differ materially from any expected future results, performance or achievements expressed or implied, by the forward looking statement.

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Appendix 4C

Quarterly cash flow report for entities subject to Listing Rule 4.7B

Name of entity

NEXSEN LIMITED

ABN	**Quarter ended ("current quarter")**
86 655 182 497	30 September 2025

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (3 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	-	-
1.2	Payments for		
	(a) research and development	(114)	(114)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs	(220)	(220)
	(f) administration and corporate costs	(429)	(429)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	-	-
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	892	892
1.8	Other (provide details if material)	199	199
1.9	**Net cash from operating activities**	**329**	**329**

Notes:

1.7 comprises receipt of payments from the Commonwealth relating to the CRC-P grant for the GBS Rapid Sensor and R&D Tax Incentive receipts

1.8 comprises GST returns not otherwise offset against other items above

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(2)	(2)

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Consolidated statement of cash flows		Current quarter $A'000	Year to date (3 months) $A'000
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-
2.2	Proceeds from disposal of:		
	(g) entities	-	-
	(h) businesses	-	-
	(i) property, plant and equipment	-	-
	(j) investments	-	-
	(k) intellectual property	-	-
	(l) other non-current assets	-	-
2.3	Cash flows from loans to other entities	-	-
2.4	Dividends received (see note 3)	-	-
2.5	Other (provide details if material)	-	-
2.6	**Net cash (used in) investing activities**	**(2)**	**(2)**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	7,453	7,453
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	-	-
3.4	Transaction costs related to issues of equity securities or convertible debt securities	-	-
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	-	-
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (provide details if material)	-	-
3.10	**Net cash from financing activities**	**7,453**	**7,453**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	423	28
4.2	Net cash from / (used in) operating activities (item 1.9 above)	329	329

Consolidated statement of cash flows		Current quarter $A'000	Year to date (3 months) $A'000
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(2)	(2)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	7,453	7,453
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash and cash equivalents at end of period**	**8,203**	**8,203**

5.	**Reconciliation of cash and cash equivalents** at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	**Current quarter $A'000**	**Previous quarter $A'000**
5.1	Bank balances	8,203	423
5.2	Call deposits	-	-
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
5.5	**Cash and cash equivalents at end of quarter (should equal item 4.6 above)**	**8,203**	**423**

6.	**Payments to related parties of the entity and their associates**	**Current quarter $A'000**
6.1	Aggregate amount of payments to related parties and their associates included in item 1	208
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-

Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments.

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7.	**Financing facilities** *Note: the term "facility' includes all forms of financing arrangements available to the entity.* *Add notes as necessary for an understanding of the sources of finance available to the entity.*	**Total facility amount at quarter end $A'000**	**Amount drawn at quarter end $A'000**
7.1	Loan facilities	-	-
7.2	Credit standby arrangements	-	-
7.3	Other (Convertible notes)	-	-
7.4	**Total financing facilities**	**-**	**-**
7.5	**Unused financing facilities available at quarter end**		-
7.6	Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.		

8.	**Estimated cash available for future operating activities**	**$A'000**
8.1	Net cash from / (used in) operating activities (item 1.9)	329
8.2	Cash and cash equivalents at quarter end (item 4.6)	8,203
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	8,203
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	n/a

Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.

8.6 If item 8.5 is less than 2 quarters, please provide answers to the following questions:

8.6.1 Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?

Answer:
Not applicable

8.6.2 Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?

Answer:
Not applicable

8.6.3 Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?

Answer:
Not applicable

Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.

Compliance statement

1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.

2 This statement gives a true and fair view of the matters disclosed.

Date: 31 October 2025

Authorised by: The Board of Directors
(Name of body or officer authorising release – see note 4)

Notes

1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.

2. If this quarterly cash flow report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report. If this quarterly cash flow report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.

3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.

4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [*name of board committee – eg Audit and Risk Committee*]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".

5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's *Corporate Governance Principles and Recommendations*, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.

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