Proposed FlashDx joint venture builds on CE-marked GBS test

Highlights:

- **Joint venture builds on existing CE-marked GBS test**
  Proposed 50:50 joint venture ("JV") will use FlashDx's existing CE-marked molecular GBS test to develop an enhanced JV product, bringing manufacturing capability and accelerating the Company's pathway to commercialisation.
- **Brings forward commercial market entry across Asia-Pacific**
  Building the enhanced JV product from FlashDx's existing CE-marked GBS diagnostic provides an advanced starting point for near-term market entry in priority markets including Hong Kong and India, leveraging Nexsen's existing clinical and large commercial network.
- **Nexsen to lead and fund the agreed US FDA and European CE-IVDR pathways, supported by FlashDx**
  Nexsen will lead and fund the regulatory programme for the enhanced JV product, supported by FlashDx, including planned US Food and Drug Administration ("FDA") 510(k) clearance and conformity under the European Union In Vitro Diagnostic Medical Devices Regulation ("CE-IVDR").
- **Expands Nexsen's GBS offering into a distinct molecular market building on established product**
  The enhanced JV product is intended for hospital and intrapartum testing, a distinct clinical setting from StrepSure's rapid lateral-flow application in antenatal screening and decentralised care. The two products are designed to address different healthcare settings, workflows and price points, broadening Nexsen's GBS market opportunity rather than competing for the same use case.
- **Large global GBS testing opportunity**
  GBS is carried by ~10–30% of pregnant women[1], across ~132 million births globally each year, creating a significant need for rapid and accessible testing closer to delivery.

Nexsen Limited (**ASX:NXN**) ("**Nexsen**" or the "**Company**"), an emerging leader in rapid point-of-care diagnostics, is pleased to announce it has entered into a non-binding term sheet with FlashDx Shenzhen Inc. ("**FlashDx**") to establish a 50:50 joint venture ("JV") for the development and commercialisation of a new and enhanced molecular Group B Streptococcus ("GBS") diagnostic test, based on FlashDx's existing CE-marked GBS Test.

The proposed JV is intended to use FlashDx's existing CE-marked molecular GBS diagnostic as the technical and regulatory foundation for an enhanced JV product, incorporating further agreed product development, including a Nexsen-contributed sample-preparation enhancement designed to improve detection at low bacterial levels, before progressing through its own planned US FDA and European IVDR regulatory pathways.

This provides the proposed JV, under license, with access to established molecular technology, manufacturing capability and regulatory know-how without having to develop a molecular system from the ground up. FlashDx will provide the established molecular technology and manufacturing capability, while Nexsen will fund and lead the agreed regulatory programme.

The enhanced JV product will sit alongside, rather than replace, Nexsen's StrepSure programme. The JV product is intended for hospital and intrapartum testing through a molecular diagnostic pathway, while StrepSure remains a separate rapid lateral-flow programme for antenatal screening and decentralised care. The two products are aimed at different clinical applications, workflows and price points.

[1] https://www.who.int/news-room/fact-sheets/detail/group-b-streptococcus-(gbs)

Managing Director, Mark Muzzin, commented:

"The proposed joint venture with FlashDx has the potential to materially accelerate Nexsen's commercial strategy. We have built strong hospital, clinical and commercial relationships across Asia-Pacific, and FlashDx gives us the opportunity to combine that network with an established molecular technology that already underpins a CE-marked GBS diagnostic.

Importantly, the JV is intended to build from that established base and develop an enhanced molecular GBS product, rather than simply take the existing FlashDx test to new market. Nexsen is also bringing its own technical contribution to the product, including an enhancement designed to improve detection where bacterial levels are low. That gives us a much more advanced starting point than developing a molecular system from scratch, while still allowing us to build a product specifically for the regulatory and commercial pathways we are targeting.

This is also a separate application from StrepSure rather than a replacement for it. The enhanced molecular product is intended for hospital and intrapartum testing, while StrepSure is being developed for antenatal screening and decentralised care. Together, they give Nexsen complementary routes into different parts of the GBS market."

Building on an established, CE-marked molecular GBS diagnostic

FlashDx is a molecular diagnostics company that has developed a proprietary, fully automated real-time PCR system designed to bring molecular testing closer to the point of care.

Its existing CE-marked GBS Test detects Group B Streptococcus from vaginal swab samples using an enclosed, sample-to-answer molecular testing system, with results available in under one hour. The test detects two separate genetic markers of the bacteria and includes a built-in quality control, which is the same approach used by the product currently cleared by the FDA for use during labour. That places it in a category the US regulator has previously cleared.

The proposed JV provides access to an established molecular GBS technology, manufacturing capability and associated intellectual property without having to develop a molecular system from the ground up. This provides a shorter pathway to regulatory expansion and commercialisation while broadening Nexsen's position in GBS diagnostics.

The parties intend to build on the existing platform to develop an enhanced JV product incorporating Nexsen-developed improvements. As part of this work, Nexsen is contributing a sample-preparation enhancement designed to release more GBS material from each sample before testing, making low levels of the bacteria easier for the molecular test to detect. This forms a core part of Nexsen's technical contribution to the JV and is intended to strengthen the performance of the enhanced product.

Bringing forward Nexsen's Asia-Pacific strategy

The proposed JV directly supports Nexsen's Asia-Pacific strategy and provides a faster pathway to address the regional demand the Company has been building.

Over the past six months, Nexsen has expanded its presence across the region through the establishment of research facilities in Hong Kong and in partnership with Universiti Malaya, together with its first hospital partnership through IHH Healthcare's Gleneagles Hospital Hong Kong.

These initiatives have established research, clinical and commercial relationships across key Asian healthcare markets. Building the enhanced JV product from FlashDx's existing CE-marked GBS diagnostic provides an established technical and regulatory starting point as the parties pursue market access in priority jurisdictions.

This could materially bring forward Nexsen's commercial plans across Asia-Pacific, providing a more advanced starting point for Nexsen's commercial strategy than developing a molecular diagnostic from the ground up, while allowing the JV to develop an enhanced product for its target regulatory and commercial markets.

Hong Kong is expected to be an initial focus, leveraging Nexsen's local presence and growing hospital network. India also represents a significant target market, subject to the applicable local regulatory pathway.

The parties currently anticipate that Nexsen will lead sales and commercial development across Asia-Pacific markets outside China.

US FDA and European CE-IVD regulatory pathways

Nexsen and FlashDx intend to pursue US FDA 510(k) clearance for the enhanced JV-GBS Test and CE-IVDR conformity. The existing CE mark for FlashDx's current GBS Test forms the established technical and regulatory foundation for the new JV product.

Nexsen will provide, through the JV, the agreed funding required to obtain the agreed regulatory approvals. Three US clinical sites already engaged by Nexsen are intended to support the US programme, providing established clinical infrastructure and relationships as the application is progressed.

FlashDx will provide the molecular testing platform, manufacturing capability and clinical trial materials required to support the JV product's regulatory development.

Proposed Joint Venture Structure

The non-binding term sheet contemplates Nexsen and FlashDx establishing a new company owned equally by the parties.

The term sheet is non-binding and the JV remains subject to the parties agreeing a detailed business plan and agreeing binding transaction documents, including a shareholders' agreement for JV-Co, a manufacturing and supply agreement between JV-Co and FlashDx.

The term sheet also contemplates:

- FlashDx will exclusively manufacture and supply the GBS Test to the joint venture;
- Nexsen will lead the regulatory program towards US FDA 510(k) clearance and provide the required funding to obtain US FDA 510(k) clearance and CE-IVDR approval;
- FlashDx will transfer the applicable FlashDx GBS cartridge-specific intellectual property into the joint venture upon those Regulatory Approvals being obtained, while retaining ownership of its platform, device, reader, manufacturing know-how and other background intellectual property;
- the joint venture will hold regulatory data, submissions and future intellectual property developed in connection with the GBS Test; and
- Nexsen and FlashDx will participate equally in the profits generated by the joint venture.

The parties will now progress definitive joint venture, manufacturing, supply, marketing and distribution agreements while commencing planning for commercial market entry and the US regulatory program.

About GBS and the global market opportunity

GBS is carried by ~10–30% of pregnant women and can cause serious, potentially life-threatening infections in newborns, including sepsis, pneumonia and meningitis.[2]

[2] https://www.who.int/news-room/fact-sheets/detail/group-b-streptococcus-(gbs)

Current screening is typically performed at 36–37 weeks of pregnancy, with samples sent to a laboratory for testing.[3] However, GBS colonisation can change over time, meaning a result obtained weeks before delivery may not reflect a woman's GBS status during labour, when transmission to the baby commonly occurs.

This creates a significant need for rapid point-of-care testing that can provide clinicians with an accurate result closer to delivery and support timely decisions around preventative antibiotics.

The market opportunity is substantial, with ~132 million births globally each year[4] and GBS estimated to contribute to around 150,000 stillbirths and infant deaths annually[5].

Nexsen's expanded GBS portfolio, combining the FlashDx molecular test with StrepSure®, provides two complementary approaches to address this global diagnostic need.

-ENDS-

ASX release authorised by the Board of Directors.

For more information, please contact:

Corporate Enquiries
e: corporate@nexsen.bio
w: www.nexsen.bio
a: Suite 1005, 4 Bridge Street, Sydney NSW 2000, Australia

Company Secretary
e: sd@nexsen.bio
p: +61 2 9174 5388

Investor Relations
e: freddie.edwards@sdir.com.au
p: +61 0 431 726 210

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.

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 product rollout 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

[3] https://www.cdc.gov/group-b-strep/testing/index.html
[4] https://population.un.org/wpp/
[5] https://www.who.int/news-room/fact-sheets/detail/group-b-streptococcus-(gbs)

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.

Neither the Company nor any person gives any representation, assurance or guarantee that the occurrence of the event expressed or implied in any forward looking statements in this document will actually occur and you are cautioned not to place undue reliance on such forward looking statements. Factors that might cause forward looking statements to differ materially from actual results, performance or achievements include, among other things, global economic conditions, economic conditions in jurisdictions in which the Company may operate or invest, credit markets, legislative fiscal and regulatory developments, the effects of continued volatility in markets and exchange rate fluctuations. The forward looking statements contained in this document speak only as of the date this document and each of the Company, respective directors, officers, employees, agents, representatives and/or advisers expressly disclaims any obligations or undertaking to release any update of, or revisions to, any forward looking statements in this document.