

25 February 2025

Next Science receives FDA Warning Letter

Next Science Limited (ASX:NXS) (“Next Science” or “the Company”) today advises that it has received a Warning Letter from the US Food and Drug Administration (FDA). The FDA regulates the manufacture, marketing and distribution of the Company’s products in the US market.

Next Science is a medical technology company focused on commercialising its proprietary XBIO™ suite of products.

The Warning Letter relates to the FDA’s inspection of the Company’s Jacksonville, Florida facility during August and September 2024. Following the FDA’s inspection, the FDA issued a list of observations, via a Form FDA-483. The Company submitted a written response addressing the FDA’s observations, including details of corrective actions that had already been undertaken as well as further actions underway. The Company has continued to regularly update the FDA on the progress of its corrective actions.

The Warning Letter reiterates the following subset of violations from the Form FDA-483:

- *Lack of marketing authorisation* – The FDA has determined that the Company does not have premarket approval pertaining to certain product marketing and labelling claims related to XPERIENCE™, BLASTX™ and SURGX™. The Company has undertaken corrective actions to address the matters raised by the FDA, including revising the product descriptions on the Company’s website and promotional materials.
- *Quality system regulation violations* – During the inspection, the FDA found that the methods used in, or the facilities or controls used for, the products’ manufacture, packing, storage or installation did not conform with the current good manufacturing practice requirements of the Quality System regulation. The Warning Letter states that the FDA cannot at the date of the letter determine the adequacy of the Company’s corrective actions and notes that the Company’s corrective actions are ongoing. The FDA states that a follow-up inspection will be needed to evaluate the implementation and effectiveness of the Company’s corrective actions.
- *Medical device reporting violations* – During the inspection, the FDA found that Next Science had failed to timely submit reports to the FDA regarding information that suggested a device marketed by the Company may have contributed to serious injury. The Warning letter notes the Company’s responses in respect of these FDA observations and states that future FDA inspections or regulatory activities will assess the implementation and effectiveness of the Company’s corrective actions.

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The Company is committed to the highest standards of compliance and is giving the utmost attention to comprehensively addressing and correcting as quickly as possible any open actions regarding the matters raised in the FDA's Warning Letter.

The Company confirms that the products it sells are safe and effective for their cleared intended uses.

Approved and authorised for release by the Managing Director and CEO.

Media & Investor Enquiries

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About Next Science

Next Science is a medical technology company headquartered in Sydney, Australia, with a research and development centre in Florida, USA. Established in 2012, the company's primary focus is on the development and continued commercialisation of its proprietary XBIO™ technology. Next Science owns 100% of the patent protected intellectual property relating to its XBIO™ technology. For further information visit: www.nextscience.com

Forward looking statements

This announcement may contain forward looking statements which may be identified by words such as "believes", "considers", "could", "estimates", "expects", "intends", "may" and other similar words that involve risks and uncertainties. Such statements are not guarantees of future performance and involved known and unknown risks uncertainties, assumptions and other important factors, many of which are beyond the control of Next Science or its Directors and management and could cause Next Science's actual results and circumstances to differ materially from the results and circumstances expressed or anticipated in these statements. The Directors cannot and do not give any assurance that the results, performance or achievements expressed or implied by the forward-looking statements contained in this announcement will actually occur and investors are cautioned not to place undue reliance on these forward-looking statements.