

# Intelligent Bio Solutions Strengthens FDA 510(k) Package with New Cybersecurity and Performance Data Ahead of Planned U.S. Market Launch

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FDA response expected within six weeks; Company remains focused on 2025 U.S. expansion

NEW YORK, Aug. 06, 2025 (GLOBE NEWSWIRE) -- Intelligent Bio Solutions Inc. (Nasdaq: INBS) ("INBS" or the "Company"), a medical technology company delivering intelligent, rapid, non-invasive testing solutions, today announced the submission of its Additional Information ("AI") response to the United States Food and Drug Administration ("FDA") as part of its ongoing 510(k) clearance process for planned entry to the U.S. market later this year. The response includes new positive data that strengthens the Company's 510(k) submission and further validates the security and performance of its innovative fingerprint sweat-based drug screening technology.

The Company's updated submission incorporates data from intensive cybersecurity testing, including penetration and electromagnetic compatibility testing. These efforts have reinforced the system's resilience across varied environments and supported targeted updates to further strengthen platform integrity and dependability. An extraordinary 10,000 hours were dedicated to the collection of new data for the submission, which included 23 detailed test reports and more than 100 supporting attachments, totaling over 1900 pages, along with over 7800 lines of data collected throughout the process.

"We are both pleased and proud to submit our recent findings to the FDA," said Peter Passaris, Vice President of Product Development at Intelligent Bio Solutions. "The quality, depth, and regulatory alignment of our current submission represents a significant advancement. Our team has shown aptitude and diligence at the highest level throughout the information request period, and we are confident in the updated package we're submitting."

INBS has also reaffirmed the accuracy of its technology using advanced quantification methods, including human

eccrine sweat testing. An Ultra-Micro Balance scale, an extremely sensitive measuring device, confirmed the system's capability to detect and analyze minute sweat volumes found in a single fingerprint.

"Securing FDA clearance has been a top priority as we look to bring our fingerprint sweat-based solution to more markets, particularly those with significant commercial potential, such as the multi-billion-dollar U.S. market," said Harry Simeonidis, President and CEO at Intelligent Bio Solutions. "The data we have gathered reflects the outstanding work of our R&D team, whose technical expertise has strengthened the case for our technology's accuracy and reliability."

INBS continues to advance its U.S. expansion strategy, prioritizing FDA clearance for its opiate test system for codeine and U.S. market entry in 2025. The Company's non-invasive drug screening technology is used across more than 450 accounts in 24 countries, supporting workplace, law enforcement and justice sectors. With 18 global distribution partners and growing awareness and adoption, INBS is steadily expanding its international presence. Entry into the multi-billion-dollar U.S. market will open significant opportunities for the Company as it pursues its global expansion plans. The Company expects a response from the FDA within six weeks.

About Intelligent Bio Solutions Inc.

Intelligent Bio Solutions Inc. (NASDAQ: INBS) is a medical technology company delivering intelligent, rapid, non-invasive testing solutions. The Company believes that its Intelligent Fingerprinting Drug Screening System will revolutionize portable testing through fingerprint sweat analysis, which has the potential for broader applications in additional fields. Designed as a hygienic and cost-effective system, the test screens for the recent use of drugs commonly found in the workplace, including opiates, cocaine, methamphetamine, and cannabis. With sample collection in seconds and results in under ten minutes, this technology would be a valuable tool for employers in safety-critical industries. The Company's current customer segments outside the US include construction, manufacturing and engineering, transport and logistics firms, mining, drug treatment organizations, and coroners.

For more information, visit <https://ibs.inc/>

#### Forward-Looking Statements

Some of the statements in this release are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995, which involve risks and uncertainties. Forward-looking statements in this press release include, without limitation, Intelligent Bio Solutions Inc.'s ability to successfully develop and commercialize its drug and diagnostic tests, realize commercial benefit from its partnerships and collaborations, and secure regulatory approvals, among others. Although Intelligent Bio Solutions Inc. believes that the expectations reflected in such

forward-looking statements are reasonable as of the date made, expectations may prove to have been materially different from the results expressed or implied by such forward-looking statements. Intelligent Bio Solutions Inc. has attempted to identify forward-looking statements by terminology, including “believes,” “estimates,” “anticipates,” “expects,” “plans,” “projects,” “intends,” “potential,” “may,” “could,” “might,” “will,” “should,” “approximately” or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. These statements are only predictions and involve known and unknown risks, uncertainties, and other factors, included in Intelligent Bio Solutions’ public filings filed with the Securities and Exchange Commission. Any forward-looking statements contained in this release speak only as of its date. Intelligent Bio Solutions undertakes no obligation to update any forward-looking statements contained in this release to reflect events or circumstances occurring after its date or to reflect the occurrence of unanticipated events.

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