

Intelligent Bio Solutions Achieves Key Milestone Ahead of Planned FDA 510(k) Submission, Advancing Toward Planned U.S. Market Entry

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Company has addressed final review items from penetration testing and finalized cybersecurity and software documentation

510(k) package submission on track for calendar H2 2026, targeting planned entry into multi-billion-dollar U.S. drug screening market

NEW YORK, July 23, 2026 (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 that it has addressed all the cybersecurity and software-related review items for its upcoming FDA 510(k) submission. This follows the Company's recent completion of independent third-party penetration testing and confirms that all review items have now been resolved. The Company is on track to submit its 510(k) notification in calendar H2 2026.

Following the April 2026 announcement that penetration testing identified no major vulnerabilities, INBS has now completed the full remediation cycle. All cybersecurity review items have been addressed, with 100% of medium-risk vulnerabilities remediated and low-risk vulnerabilities reduced from 11 to 2. The remaining items are supported by a comprehensive risk-based justification confirming that there is no impact on device safety, effectiveness, or performance. In parallel, all 19 software bill of materials (SBOM) vulnerabilities have been fully resolved, with documentation and system configuration aligned with FDA guidance. Independent third-party verification confirmed there were no remaining issues. Together, these outcomes materially reduce regulatory risk and further strengthen the Company's 510(k) package ahead of its planned calendar H2 2026 filing.

"This is a meaningful de-risking event for INBS and an important milestone in our progression toward planned U.S. market entry. Having completed the independent penetration study, we have now resolved all cybersecurity and software-related issues," said Harry Simeonidis, President and CEO at Intelligent Bio Solutions. "We believe we are in a strong position as we advance through the remaining stages of the FDA review process and move toward our planned 510(k) submission in the second half of 2026."

The Company's 510(k) package targets codeine detection as the initial indication. Clearance is expected to open opportunities for the Company in the U.S. market beyond Forensic Use Only settings. The U.S. drug screening market represents a multi-billion-dollar annual opportunity spanning workplace testing, criminal justice, pain management, law enforcement, and substance abuse treatment. With its manufacturing partnership with Syrma Johari MedTech expected to deliver annual production cost savings of more than 40% and an expected annual gross margin improvement of approximately 20 percentage points, INBS is building the operational and financial infrastructure to support a scalable U.S. commercial launch following FDA clearance.

The Intelligent Fingerprinting Drug Screening System collects fingerprint sweat samples in seconds and delivers results in under ten minutes. The process is non-invasive, hygienic, and occurs at the point of collection. This innovative technology is designed to detect recent drug use up to 16-24 hours before testing, and in other countries, is being used to screen for opiates, cocaine, methamphetamine, and cannabis. The System is already commercially deployed outside the U.S. across workplace, law enforcement, and government settings.

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 U.S. 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, and involve risks and uncertainties. Forward-looking statements in this press release include, without limitation, statements regarding Intelligent Bio Solutions Inc.'s ability to successfully develop and commercialize its drug and diagnostic tests, realize commercial benefits from its partnerships and collaborations, secure regulatory clearance or approvals, and timelines to enter the U.S. market, among others. Although Intelligent Bio Solutions Inc. believes that the expectations reflected in such forward-looking statements are reasonable as of the date made, actual results may differ materially from those expressed or implied by such 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," and "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, including those described in Intelligent Bio Solutions' public filings with the U.S. Securities and Exchange Commission. Any forward-looking statements contained in this release speak only as of the date of this release. 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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