



Intelligent Bio Solutions Inc. Announces Progress Toward Completion of Clinical Study Plan Required for FDA 510(k) Submission

September 5, 2024

NEW YORK, Sept. 05, 2024 (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 its progress toward completion of the clinical study plan required for its FDA 510(k) submission.

In August 2024, INBS announced its partnership with CenExel to perform the method comparison study as part of the Company's clinical study plan. The study involves the recruitment of 135 healthy adult subjects across three sites under an IRB-approved protocol and comparing the results of fingerprint sweat opiate screening tests with those obtained using a validated, traceable liquid chromatography-mass spectrometry (LC-MS/MS) method in a laboratory.

The Company has successfully completed approximately one-third of the subject enrollment targets for its method comparison study, including screening, consenting, and fingerprint sweat specimen collection activities. Additionally, the Company recently completed the in-clinic portion of a pharmacokinetic (PK) study on opiates in human fingerprint sweat and is currently analyzing the collected specimens and data from the study.

Harry Simeonidis, President and CEO at INBS, commented, "Our team and CRO partner are working together effectively to remain on track with our plan to complete the in-clinic portion of the method comparison study by the end of September. This progress aligns with our overarching goal of preparing a 510(k) submission for the FDA in the fourth calendar quarter of 2024."

Through these clinical studies, the Company intends to demonstrate that the Intelligent Fingerprinting Drug Screening System is easy to use and performs accurately in the hands of intended users to detect the presence of opiates.

About Intelligent Bio Solutions Inc.

Intelligent Bio Solutions Inc. (NASDAQ: INBS) is a medical technology company delivering innovative, 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 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. Additionally, the Company's biosensor platform has the potential to test for various indications, ranging from immunological conditions to communicable diseases. The Company's current customer segments include construction, manufacturing and engineering, transport and logistics firms, drug treatment organizations, and coroners.

For more information, visit: <http://www.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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