



Intelligent Bio Solutions Partners with CenExel to Conduct Clinical Study as Part of FDA 510(k) Pathway

August 1, 2024

NEW YORK, Aug. 01, 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 partnership with [CenExel](#), a nationwide clinical research site network, to perform a method comparison clinical study as part of the Company's FDA 510(k) clinical study plan.

The Company's method comparison study will recruit 135 healthy adult subjects across three sites under an IRB-approved protocol and compare the results of fingerprint sweat opiate screening tests to the results from a validated, traceable liquid chromatography mass spectrometry (LC-MS/MS) method, widely accepted as the gold standard for such studies.

Harry Simeonidis, President and CEO of Intelligent Bio Solutions, commented, "We are pleased to announce our partnership with CenExel and the initiation of the method comparison study, marking the final phase in our clinical study plan. Over the past two months, we have made substantial progress and are steadily getting closer to filing our 510(k) submission with the FDA. We remain on track for our planned submission to the FDA in the fourth quarter of this calendar year. I commend our dedicated team and clinical study partners for their immense effort and commitment to ensuring the smooth execution of our clinical study plan." Stuart Goldblatt, Chief Executive Officer at CenExel, stated, "CenExel is excited to commence this clinical trial to test this innovative device with the potential to provide rapid and non-invasive testing for opiates."

The Company recently completed the in-clinic portion of a pharmacokinetic (PK) study on opiates in human fingerprint sweat. Through the method comparison study, the Company intends to demonstrate that the [Intelligent Fingerprinting Drug Screening System](#), which comprises the Intelligent Fingerprinting Drug Screening Cartridge and DSR-Plus fluorescence reader, performs accurately in the hands of intended users to detect the presence of opiates. The Company plans to commence the method comparison study in August 2024.

About CenExel

CenExel provides unparalleled medical and scientific support in the design and execution of clinical trials. CenExel's therapeutic area focus, attention to detail, and auxiliary services assure quality, reliable results and help it to consistently achieve and exceed patient recruitment goals. CenExel Centers of Excellence have conducted thousands of studies, the variety and complexity of which have resulted in a vast depth of experience and insight for the Principal Investigators and research staff in each facility. The CenExel Centers of Excellence deliver the engagement, expertise, and results to ensure clients achieve their clinical research goals.

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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