UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of
the Securities Exchange Act of 1934

Date of Report (Date of Earliest Event Reported): **February 28, 2024**

INTELLIGENT BIO SOLUTIONS INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-39825**	**82-1512711**
(State of Incorporation)	(Commission File Number)	(IRS employer identification no.)

142 West, 57th Street, 11th Floor
New York, NY 10019
(Address of principal executive offices, including zip code)

Registrant's telephone number, including area code: **(646) 828-8258**

N/A
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.01 par value	INBS	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2). Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure.

On February 28, 2024, Intelligent Bio Solutions Inc. (the "Company") issued a press release (the "Press Release") announcing its partnership with Cliantha Research, a full-service Clinical Research Organization (CRO), to perform a pharmacokinetic (PK) study forming part of the Company's FDA 510(k) clinical study plan.

A copy of the Press Release is attached hereto as Exhibit 99.1 and is incorporated herein by reference. The foregoing disclosure is qualified in its entirety by the full text of the Press Release.

The information disclosed under Item 7.01, including Exhibit 99.1 attached hereto, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 and shall not be deemed incorporated by reference into any filing made under the Securities Act of 1933, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

No.	Description
99.1	Press Release, dated February 28, 2024
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: February 29, 2024

INTELLIGENT BIO SOLUTIONS INC.

By: */s/ Spiro Sakiris*
Name: Spiro Sakiris
Title: Chief Financial Officer

Exhibit 99.1

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

NEW YORK, February 28, 2024 – Intelligent Bio Solutions Inc. ("INBS" or the "Company") (Nasdaq: INBS), a medical technology company delivering intelligent, rapid, non-invasive testing solutions, today announced its partnership with Cliantha Research, a full-service Clinical Research Organization (CRO), to perform a pharmacokinetic (PK) study forming part of the Company's FDA 510(k) clinical study plan.

The Company's PK study will recruit 40 healthy adult subjects under an IRB/EC and regulatory approved protocol and compare the amounts of opiates in fingerprint sweat versus blood, oral fluid and urine specimens following the medically supervised administration of drugs. All fingerprint sweat, blood, oral fluid and urine specimens will be analyzed by a validated, traceable liquid chromatography mass spectrometry (LC-MS/MS) method, widely accepted as the gold standard for such studies. The fingerprint sweat specimen will be screened using INBS' Intelligent Fingerprinting Drug Screening System comprising the Intelligent Fingerprinting Drug Screening Cartridge and DSR-Plus fluorescence reader and compared to the LC-MS/MS results.

The start of the clinical study plan marks an exciting milestone for the Company as it advances on its 510(k) pathway. Harry Simeonidis, President and CEO at Intelligent Bio Solutions, commented, "We are pleased to share news of our partnership with Cliantha and progress on our 510(k) journey. Initiating our clinical studies plan represents a critical milestone for our organization. We have developed a detailed plan that we are committed to executing, and while there is considerable work ahead, we have taken the crucial first step in this process. Our focus is on ensuring we remain on track for our planned entry into the US market and expand access to our innovative screening solution." Dr Anne Marie Salapatek, Chief Scientific Officer and Executive Vice President at Cliantha Research, stated, "At Cliantha, we are excited to commence this rigorous and controlled clinical trial to test this innovative device with potential to provide rapid and non-invasive testing for opiates."

In June 2023, the Company announced it had received guidance from the FDA regarding the regulatory classification of its Intelligent Fingerprinting Drug Screening Cartridge. The FDA provisionally determined that the cartridge falls within 21 CFR 862.3650, Opiate Test System, a Class II type device that requires the submission of a pre-market notification 510(k) and the FDA's clearance prior to marketing.

The Company intends to demonstrate through the PK study that the fingerprint sweat measurement is a suitable proxy for measurements obtained from blood, oral fluid, or urine specimens to detect the presence of opiates. Recruitment and screening of subjects for the PK study are anticipated to take place in March and April 2024, with studies set to begin in May 2024. Sample analysis is projected to conclude by the end of June 2024.

About Cliantha

Cliantha Research Limited is a full-service, global Clinical Research Organization (CRO) providing comprehensive and integrated offerings in Clinical Endpoint Trials (Phase I – IV), Bioequivalence (BA/BE) Studies, Safety/Phase I/ FIM (SAD/MAD/POC) Studies, and those studies involving Personal Healthcare products. Cliantha specializes in Nutraceutical Products, Dermatology, Respiratory, Allergy, and Ocular trials. Cliantha also offers a state-of-the-art Bioanalytical Laboratory.

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 up to 130 indications, ranging from glucose to immunological conditions and 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.

Company Contact:

Intelligent Bio Solutions Inc.
info@ibs.inc
LinkedIn | Twitter

Media Contact:

Cheryl Billson
Comma Communications
cheryl.billson@commacomms.com
+44 (0)7791 720460