

# GBS Inc. Announces its Pre-Submission package is with the FDA

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NEW YORK, Oct. 13, 2021 (GLOBE NEWSWIRE) -- GBS Inc. (Nasdaq: GBS), a life sciences company developing non-invasive, real-time diagnostic testing for patients and their primary health practitioners at point-of-care, today announced it has filed a Pre-Submission package with the United States (US) Food and Drug Administration (FDA). The purpose of this pre-submission is to confirm with the FDA that GBS is following the proper steps to conduct the clinical studies enabling it to develop the glucose biosensor according to the FDA regulatory standards.

The pre-submission package will allow the FDA to review the Company's clinical trial plans and protocols while also providing a forum for feedback on these clinical studies as it pursues regulatory approval. The proposed three step clinical plan involves generation of prospective data, the initial objective is to explore the relationship between salivary glucose and plasma glucose as well as the time course between the two. The next phase objective is the development of the algorithm between plasma and salivary glucose and the final stage will confirm the algorithm and generate data for regulatory submission.

For the first phase the Company intends to recruit 20-40 subjects and is currently finalizing arrangements with US based clinical research sites, in order to commence its program pending regulatory approval.

GBS is developing a Saliva based Glucose test on the Biosensor Platform to be used in the point-of-care setting. The Company intends to provide people living with diabetes a more favorable solution to finger-prick blood glucose testing.

This alternative test offers a pain-free option to current testing methods by using an Australian developed organic thin film transistor, incorporating Glucose Oxidase (GOX) as the recognition element to initiate an electrochemical reaction that produces an electrical signal to display glucose measurements in real-time on a mobile app or

dedicated device.

In July GBS was awarded a USD \$4.7 million, Australian Federal Government scientific grant to fund the build out of a Biosensor manufacturing facility. GBS's grant project was identified as one of six National Manufacturing Priorities identified by the Government under its Modern Manufacturing Strategy (MMS).

"The number of people living with diabetes is expected to increase to 700 million by 2045 and in 2019 an estimated 1.5 million deaths were directly caused by this disease, so it is imperative people living with diabetes have the means to regularly monitor and manage their glucose levels in a painless and easy way," said Harry Simeonidis Chief Executive Officer of GBS.

"It has always been our mission to create simple to use, life-changing diagnostics that can be put into the hands of people who need them the most, and our world-first Biosensor technology is the first step in fulfilling that mission."

About GBS Inc.

GBS Inc. is a life sciences company developing non-invasive, real-time monitoring and diagnostic tests for patients and their primary health practitioners. With the world-first Biosensor Platform, GBS Inc. is developing and launching diagnostic tests urgently needed to help people living with diabetes.

For more information, please visit [www.gbs.inc](http://www.gbs.inc) or follow GBS Inc. on **Twitter** and **LinkedIn**.

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, GBS Inc.'s ability to develop and commercialize its diagnostic tests, realize commercial benefit from its partnerships and collaborations, and secure regulatory approvals, among others. Although GBS, 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. GBS 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 the Company's public filings filed with the Securities and Exchange Commission. Any forward-looking statements contained in this release speak only as of its date. We undertake 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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