

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 10-K

(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended **June 30, 2021**

or

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission File Number 001-39825

GBS Inc.

(Exact name of Registrant as specified in its Charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

82-1512711

(I.R.S. Employer
Identification No.)

420 Lexington Ave, Suite 300 New York, NY

(Address of principal executive offices)

10170

(Zip Code)

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

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

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
Common Stock, par value \$0.01 per share	GBS	Nasdaq Global Market

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES NO

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. YES NO

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES NO

Indicate by check mark whether the Registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). YES NO

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

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.

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). YES NO

The aggregate market value of the Common Stock (based on the closing price of these shares on the Nasdaq Global Market) on December 31, 2020, the last business day of the registrant's most recently completed second fiscal quarter, held by nonaffiliates, was \$35,140,017.

As of September 13, 2021, there were 14,882,522 of the registrant's Common Stock issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Information required by Part III of this Annual Report on Form 10-K is incorporated by reference to the Registrant's Definitive Proxy Statement for its 2021 Annual Meeting of Shareholders, which proxy statement will be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year covered by this Form 10-K.

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PART I

Cautionary Note Regarding Forward-Looking Statements

All statements other than statements of historical fact or relating to present facts or current conditions included in this Annual Report on Form 10-K are forward-looking statements. Forward-looking statements include, but are not limited to, statements regarding expectations, hopes, beliefs, intentions or strategies regarding the future. In addition, any statements that refer to projections, forecasts or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. These statements may include words such as “anticipate,” “estimate,” “expect,” “project,” “plan,” “intend,” “believe,” “may,” “should,” “can have,” “likely” and other words and terms of similar meaning, but the absence of these words does not mean that a statement is not forward-looking.

The forward-looking statements contained in this Annual Report on Form 10-K are based on our current expectations and beliefs concerning future developments and their potential effects on us. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in “Risk Factors.” Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the future events and trends discussed in this prospectus may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. The events and circumstances reflected in the forward-looking statements may not be achieved or occur. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance, or achievements. Except as required by the federal securities laws, we are under no duty to update any of these forward-looking statements after the date of this Annual Report on Form 10-K or to conform these statements to actual results or revised expectations.

In this Annual Report on Form 10-K, the terms “we,” “us,” “our,” “Company,” or “GBS” refer to GBS Inc. together with its wholly owned subsidiaries.

ITEM 1. BUSINESS.

Overview

GBS Inc. and its wholly owned subsidiary, GBS Operations Inc. were formed on December 5, 2016 under the laws of the State of Delaware. Our headquarters are located in New York, New York.

We are a biosensor diagnostic technology company operating across the Asia-Pacific Region (“APAC”) and an interest in the USA Region with the biosensor platform comprising of biochemistry, immunology, tumor markers, hormones, and nucleic acid diagnostic modalities, and worldwide with our COV2 test.

Our objective is to introduce and launch initially the Saliva Glucose Biosensor (referred to as the “SGB”), the diagnostic test that stems from the Biosensor Platform that we license from Life Science Biosensor Diagnostics Pty Ltd (“LSBD” or “Licensor”) in our regions and the COV2 test globally. This will be followed by developing the platform to its full capacity testing across the diagnostic modalities of Immunology, Hormones, Chemistry, Tumor markers and Nucleic Acid tests. We are a 42.6% (as of June 30, 2021) owned (by voting rights) affiliate of LSBD, an Australian company that owns the worldwide intellectual property rights to the biosensor platform.

Highlights of Achievements

Our major highlights of achievements since listing the Company on the NASDAQ Global Market in December 2020 are:

- Successfully being awarded \$4.7 million (excluding GST/VAT) in Medical Products Priority Grant funding by the Australian government to fund a high-tech manufacturing facility, identified as one of six National Manufacturing Priorities
- Harvard Longwood Campus Institutional Review Board approval to perform a clinical study with patient samples with the SARS-CoV-2 Antibody Biosensor
- Securing of an option to acquire the North America license for Glucose Testing
- Receiving \$578,000 in Australian government support as a Research and Development (R&D) incentives for the development of the technology
- Results of global voice of customer survey of more than 300 patients living with diabetes verified
 - an overall 90% desirability for the Saliva Glucose Biosensor
 - 7 out of 10 patients “seriously interested in purchasing the product upon its release
 - 3 out of 10 wanting to be placed on the waiting list ahead of release
- L.E.K. Consulting agreement to identify suitable partnership opportunities for sales and distribution in the APAC region

The Saliva Glucose Biosensor

The SGB uses saliva to measure glucose non-invasively. When the SGB interacts with saliva, an electrochemical reaction is initiated that produces an electrical signal directly correlated to the amount of glucose present in the saliva. This measurement is then converted into a real-time saliva glucose reading by a software app on a smart device or a dedicated smart reader for those that do not possess a compliant and compatible smart device. The reading may then be stored in our proprietary cloud-based digital information system.

The APAC Region includes over 164 million people living with diabetes, which accounts for 38% of the world’s diabetic population. Rapid urbanization, unhealthy diets and increasingly sedentary lifestyles have resulted in ever increasing rates of obesity and diabetes across the region.

Self-testing blood glucose monitors were introduced to the market in the 1970s and, since then, the method of glucose self-monitoring has not meaningfully changed. The industry remains dominated by invasive methods that ultimately use blood or interstitial fluid to measure glucose. We believe the methodology of the SGB represents a breakthrough in glucose monitoring as it represents the only non-invasive, painless and cost-effective saliva-based method of measuring glucose levels. The biosensor technology has been developed over several decades of university-based scientific research and has been extensively referenced in scientific literature.

The SGB is an organic transistor, which in its structure embeds the glucose oxidase enzyme (referred to as “GOX”). When the single-use SGB interacts with saliva it initiates an electrochemical reaction, producing an electrical signal directly correlated to the amount of glucose present in the saliva. This measurement is then converted into a real-time saliva glucose reading, through the biosensor app installed on a smart device or a dedicated reader.

The patent protected SGB is able to detect glucose in saliva at concentrations between 8 and 200 μM and exhibits linear glucose sensing characteristics at these concentrations, sensing glucose at levels 100 times lower than blood.

In our development of the SGT, we aim to go beyond the innovation of changing the sampling medium from blood to saliva, and further create value for the patient and the payers by decreasing the cost of managing diabetes, improving the outcomes of the disease and providing convenience in testing methodology. This will be achieved by directly transferring the SGB reading from the smart device or dedicated reader to our proprietary digital information system, which is cloud-based to enable every patient the option to create their own medical record where the SGB results will be uploaded.

Our digital information system is intended to be interfaced to an artificial intelligence system and will be able to, at the patient’s or authorized care giver’s direction, disseminate patient data to a remote caregiver, a service for consultation or to any other individual with whom the patient chooses to share his or her glucose level measurements. We believe patients and payers will be able to leverage our digital information system to decrease cost and improve outcomes and convenience.

With the SGB we aim to drive economic value beyond the revenue stemming from the sale of the SGB units – it also allows for monetization and the creation of separate revenue streams from the patient network and other data that resides within our digital information system, by way of the following:

- Data usage. The usage of the data, and the analysis and interpretation of the data, to improve patients' conditions and leveraging this insight to improve patient care.
- Safe data sharing. The provision of data sharing services between users/patients, authorized care givers and authorized medical practitioners.
- Data collection. The collection of anonymized data, its aggregation with other data from multiple sources and multiple health devices and its combination with non-health data.

We plan to leverage this usage, safe sharing and collection of data in the following four revenue-generating channels:

Direct Monetization Channel. This channel focuses on the development of revenue based on commercial relationships for the use of anonymized and compliant information derived from data generation. These services may include, but will not be limited to:

- Fee for service, per performed action by pharma, or other commercial partners.
- Subscription, regular recurring payments for continued access to service.
- Prescription, value acknowledged by payer reimbursement per active user.
- Third party coverage, other industry/retail players pay fee for their own customers.
- Risk sharing/profit sharing, success-based payment models.
- Advertising, third party ads tailored to demographic data leveraging characteristics unique to channel.
- Added value of GBS brand loyalty.

Commercial Adjacencies Channel. This channel focuses on the development of revenue from data generated through patient engagement and market insights from a clinical and medical perspective. These services may include, but will not be limited to:

- Medical – Generation of Patient Reported Outcomes, or “PROs”.
- Data – Market insights, clinical trial recruitment for third parties, e.g., pharmaceutical companies or clinical research organizations.
- Consumer – e-commerce platform, third party customer care, advertising.

Product and Service Bundles Channel. This channel focuses on ancillary revenue generated through bespoke service opportunities across the industry, for example, by working with insurers to develop products that integrate the usage of testing as part of their service offering. These services may include, but will not be limited to:

- Over-the-counter model.
- Bundle payment model with insurance subsidy.
- Pay for outcomes model.

Core Operations Synergy Channel. Through combining the data generation with the use of artificial intelligence, we expect to have a deep insight into our customer base, providing an elevated level of customer insight. It is expected that this insight will drive high customer retention levels and generate a considerable number of broader revenue opportunities through direct and specific interaction with our customer base. These opportunities may include, but will not be limited to:

- Direct access to customers for better experience in customer care.
- Peer learning and support to decrease customer care resource commitment.
- Direct market and customer insights (including better understanding of customer journey).
- More customer data for targeted marketing & marketing impact monitoring.
- New cost effective, digital marketing channel enabling agile marketing approach.
- PRO data to support unique marketing claims.
- Higher engagement, customer loyalty and customer lifetime value.
- Consumer driven innovation and customer involvement in development.
- Involvement in testing & refining to develop demand-oriented products rapidly.
- Easy and fast clinical evaluation recruitment.
- PRO to support regulatory approval / market access for platform tests under development.

The SGB has been under continuous development for over six years, first by the University of Newcastle, Australia, then by the Licensor and us. The SGB development program is currently at the validation stage, which is Phase 5 of development of the SGB, this includes the stages of design & process development to enable the testing needed to verify and validate the final product. This stage involves implementation of the clinical evidence module, which incorporates the commercial production of the investigative biosensor devices to commence the clinical evaluation of analytical performance of the device and generate the clinical evidence necessary to gain regulatory approval.

On May 1, 2020, the Licensor filed a submission with the FDA for the Saliva Glucose Biosensor Diagnostic Test, currently in development as a point-of-care test intended to replace blood glucose testing for diabetes management. Following the 513(g) submission to the FDA (Submitted May 01, 2020), it was determined that the company could seek the De Novo application pathway for the Saliva Glucose Biosensor Diagnostic Test, we were appointed an expert contact person, Acting Branch Chief from the Diabetes Diagnostic Devices Branch. We have further commenced planning discussions with the FDA Office of In Vitro Diagnostics and Radiological Health and the Office of Product Evaluation and Quality pertaining to the clinical development and study plan of the Saliva Glucose Biosensor. . We expect to leverage synergies from the planned approval process with the FDA within the Asia Pacific region, where China has the highest number of people with diabetes. We will first seek regulatory approval with the NMPA of China. However, we intend to apply for regulatory approval in each jurisdiction across the APAC Region. Recently, we entered into non-binding memoranda of understanding with two large distributors in China, which express our intent to enter into definitive agreements to collaborate on the manufacture, regulatory approval, and distribution and sale of, and the medical affairs, marketing, and identification of strategic opportunities for, the SGB in China.

The SGB is manufactured using modified reel-to-reel printing technology that was developed at the Australian National Fabrication Facility. This technology allows mass volume printing at a low cost. Previous research published in the journal *Solar Energy Materials and Solar Cells* has shown that the cost of manufacture of printed organic electronic devices (like the SGB) using mass volume printing is \$7.85 per square meter, with an uncertainty of 30%. The size of the printed biosensors is approximately one square centimeter, resulting in a manufacturing cost per biosensor of approximately \$0.001.

We anticipate that the non-invasive nature of saliva-based glucose testing will make patients more amenable to glucose monitoring, with the expected result of increasing the number of times a patient tests per day. The data generated by the SGB, combined with the interface of the smart device or dedicated reader with our digital information system and the artificial intelligence feedback, will allow the patient to achieve better glucose control through a practical understanding of lifestyle factors that affect glucose levels, thereby helping prevent or delay diabetes complications and ultimately personalizing diabetes management.

The COV2 Biosensor

The COVID-19 pandemic will not simply go away, and we believe it will remain with us for many years. Development of an improved antibody assays to detect prior infection with SARS-CoV-2 has been identified as one of the top unmet needs in the ongoing COVID-19 pandemic response. Precise knowledge of SARS-CoV-2 infection at the individual level can potentially inform clinical decision-making, whereas at the population level, precise knowledge of prior infection, immunity, and attack rates (particularly asymptomatic infection) is needed to prioritize risk management decision-making about social distancing, treatments, and vaccination (once the latter two become available). If saliva can support measurements of both the presence of SARS-CoV-2 RNA26-28 as well as antibodies against SARS-CoV-2, this sample type could provide an important opportunity to monitor individual and population-level SARS-CoV-2 transmission, infection, and immunity dynamics over place and time.

We anticipate there to be 3 different applications for the near future:

- *Population Screening* - SARS-CoV-2 antibody testing is urgently needed to estimate the incidence and prevalence of SARS-CoV-2 infection at the general population level. Precise knowledge of population immunity could allow government bodies to make informed decisions about how and when to relax stay-at-home directives and to reopen the economy.
- *Diagnosis* – The COV2 Biosensor test can be used as a complement to the (RNA) virus detection tests for patients presenting late after symptoms onset to healthcare facilities and where virus detection tests are negative despite strong indications of infection. In addition, they can potentially be used for informing the decision on discharge of patients who recovered from SARS-CoV-2 infection but remain RNA-positive by RT-PCR for a long time after symptoms have subsided. The degree of protective immunity conferred by or correlated with the antibodies detected in subjects with past SARS-CoV-2 infection is still under investigation. Once this is clarified, the COV 2 antibody tests could be, together with the (RNA) direct virus detection, an essential tool in de-escalation strategies. Currently antibody tests are used for sero-epidemiological surveys and studies.
- *Post vaccination screening* - To assess the degree of the elicited potent antigen-specific antibody responses, to COV2 vaccines when developed and administered to humans.

We believe our COVID test will have significant advantages and we anticipate it will be a ground-breaking development in the management of COVID19.

Based on a recent paper publicly available and authored by the team at Johns Hopkins Department of Environmental Health and Engineering, Bloomberg School of Public Health, results indicate it is feasible to accurately measure the salivary IgG response to identify individuals with a prior SARS-CoV-2 infection. A saliva-based approach could serve as a non-invasive approach for accurate and large-scale SARS-CoV-2 “sero”-surveillance.

A saliva antibody test can greatly increase the scale of testing—particularly among susceptible populations—compared to blood and could clarify population immunity and susceptibility to SARS-CoV-2. The team at John Hopkins further demonstrated in the laboratory that when saliva was collected ≥ 10 days post symptom onset, the anti-SARS-CoV-2 IgG assay detects SARS-CoV-2 infection with 100% sensitivity and 99% specificity. In addition, the team demonstrated that the temporal kinetics of SARS CoV-2-specific IgG responses in saliva are consistent with those observed in serum and indicate that most individuals seroconvert approximately 10 days after COVID-19 symptom onset or approximately two weeks post-presumed infection.

By utilizing the biosensor platform for detecting COV2 we expect to have lower detection limits, improve on sensitivity and specificity characteristics of current diagnostic methods, be able to provide real time results at the point of care and provide quantitative results as opposed to negative or positive which is how other POCT report the results.

Accurate and scalable point-of-care (POC) tests for the diagnosis of COVID-19 would increase the scope for diagnosis to be made in the community and outside the laboratory setting They would have the potential to reduce the time to obtaining an actionable result, could support early identification of those with COVID-19 and could also support appropriate use of isolation resources, infection control measures, and recruitment into clinical trials of treatments.

Our Products

Biosensor Platform Technology

The “*Biosensor Platform*” on which the SGB is based is a modified Organic Thin Film Transistor, or “*OTFT*,” architecture. The basis OTFT structure consists of a source and drain electrode, a semiconducting layer, a gate electrode, an optional separation (or dielectric) layer, all printed on a substrate material and superimposed by a polyelectrolyte membrane/enzyme layer onto which the analyte is placed. The layered biosensor architecture and fabrication allows the recognition element within the biosensor to be exchanged. The sensing principle for the COV2 Test is the same as the Salivary Glucose Test, amperometric: target biomolecules generate an electrical current that is detected by the transistor. The major difference is that only the GOX layer is substituted with an alternative layer containing a different recognition element, in this case the COV2 Protein that enables the detection of COV2 antibodies. The underlying layers of the Organic Thin Film Transistor (OTFT) remain unchanged. Hence this significantly simplifies our development effort to make a blood and saliva based COV2 diagnostic test.

Therefore, the glucose oxidase (“GOX”) element of the biosensor used to detect glucose in the case of the SGB can be substituted with antibodies specific to cancer biomarkers, immunological tests, hormones and other biomarkers.

The Saliva Glucose Test

The SGT consists of:

- The SGB – a single use disposable saliva biosensor, and
- Software app on a smart device or a dedicated reader that interfaces the SGB with our digital information system.

The Saliva Glucose Biosensor (SGB)

The SGB was invented at the COE at the University of Newcastle, Australia. Patents for the SGB technology have been granted in the United States (9,766,199) and China (ZL201380022888.2). The core innovative characteristic of the SGB is the sensitivity of the glucose biosensor that enables it to detect glucose in saliva at concentrations between 8-200 μM and exhibits linear glucose sensing characteristics at these concentrations, sensing glucose at levels 100 times lower than in blood.

The SGB interacts with the glucose in the saliva and initiates an electrochemical reaction, producing an electrical signal directly correlated to the amount of glucose present in the saliva. This measurement is then converted into a real-time saliva glucose reading, through the software app installed on a smart device or a dedicated smart reader. The data may then be transferred to our digital information system coupled with an artificial intelligence system, which will provide the patient with personalized healthcare advice enabling a practical understanding of lifestyle factors that may affect their glucose levels.

The SGB utilizes the GOX enzyme for signal generation. The enzyme acts on glucose, triggering a series of reactions that yields two protons (i.e., electrical current) for each interaction with a substrate molecule. The biosensor therefore produces an electrical current (i.e., signal) that is proportional to the concentration of glucose in the sample. The GOX enzyme is well-suited for monitoring glucose levels and it has been used extensively in commercially available products. Its mode of action, including the direct signal correlation with the amount of glucose, has been reviewed in numerous scientific journal articles, including in *Biosensors and Bioelectronics*, *International Journal of Biochemistry & Cell Biology* and *Journal of Diabetes Science and Technology*. Additional scientific journal articles in *Applied Physics Letters* have described the biophysical characterization of the SGB and further support the claim that its signal directly correlates with the glucose concentration in the sample.

The direct correlation between glucose concentration and sensor signal is independent of the type of sample under examination (i.e., blood or saliva). The use of saliva as a meaningful proxy for estimating blood glucose level is supported by extensive scientific literature that has investigated the physiological glucose concentration in both biological fluids and overwhelmingly reported a strong correlation, including in articles published in independent journals such as the *Journal of Obesity*, the *Journal of International Oral Health*, the *Journal of Clinical and Experimental Dentistry*, the *Journal of Oral Biology and Craniofacial Research*, *Diabetes & Metabolic Syndrome*, the *Journal of Biological Regulators and Homeostatic Agents and Diabetologia*, among others. However, a few isolated articles have reported finding no significant correlation, including articles in the *Journal of Clinical and Diagnostic Research* and the *Journal of Oral Science*. Overall, we believe there is abundant clinical evidence in independently reviewed scientific literature that saliva can be utilized as a non-invasive alternative to blood to monitor glycemic status in diabetic patients.

The basic OTFT structure consists of a source and drain electrode on a semiconducting material which is itself separated from a third gate electrode by a thin insulating layer. The COE has pioneered the fabrication of these novel biosensors based on integrating biomolecules, such as enzymes, directly into the architecture of organic transistors; producing electronic devices with both high sensitivity and high specificity for the target analyte. In these biosensors, a molecular recognition element can simply be integrated directly into the device structure, and in the case of the SGB, the recognition element is GOX.

High quality OTFTs have been routinely fabricated at the materials node of the Australian National Fabrication Facility. The COE has pioneered the fabrication of novel biosensors based on integrating biomolecules, such as enzymes, directly into the architecture of organic transistors; producing electronic devices with both high sensitivity and high specificity for the target analyte and in this case, glucose.

The development of an intermediate device that communicates to the smart device has been completed. The intermediate device emulates a glucometer, providing the mechanical and electrical interfaces to receive and power the SGB as well as the required circuitry for accurately reading the amperometric signals. We intend to transfer the responsibilities of the intermediate device to the SGB. A possible route to achieve this technical aim is to leverage near-field-communication, or “NFC,” tags, available off the shelf and routinely used in consumer electronics, to power the SGB and implement the communication protocol. NFC tags are compatible with flexible electronics and widely used in “internet of things” applications in view of their low cost. We believe that NFC tags suitable for integration with the SGB can be purchased for approximately \$0.10 per tag, even at low volumes. The cost of electronic components is well known to significantly reduce as volume increases. Due to the large expected volumes of the SGB, we believe it is reasonable to assume that the cost of suitable NFC tags will be viable and less than \$0.04.

The Licensor owns patents in Australia, China and the United States protecting the following technological claims of the SGB: the architecture of a biofunctional organic thin film transistor device comprising a gate electrode, a dielectric layer, a partially-organic semiconducting layer, a source electrode, a drain electrode, a substrate and an enzyme; the method for producing the organic thin film transistor device; and the method for determining the concentration of a compound in a sample by interpreting the amperometric signals generated by the device. The Chinese and the United States patent belong to the same patent family, originating from the Australian patent. As such, all of the patents relate to identical technology claims.

History and Background of the Saliva Glucose Biosensor

The SGB leverages the decades of history of all-polymer printed OTFTs. Through the research conducted at COE, this OTFT technology has been transformed into a medical device and expected to conform to the highest medical device standards globally. The SGB is based on a modified OTFT architecture incorporating GOX as the recognition element. It has been demonstrated that the SGB exhibits linear glucose sensing at concentrations of 8-200 μM (micro molar) offering a saliva-based test for diabetic monitoring and diagnosis.

Fundamentals of the biosensor technology have been well-characterized and have deep scientific foundations. Since their invention in 1947, transistors have dominated the mainstream microelectronics industry. Field Effect Transistors, or “FETs,” are a class of transistor in which the current between a pair of source and drain electrodes separated by a semiconductor is controlled by a voltage applied to a third electrode known as the gate. The gate electrode is separated from the source-drain region by a thin (~100 nm) insulating dielectric region and thus is coupled to the semiconductor. By altering the bias voltage applied to the gate region, the source-drain region can be altered from conducting to insulating and thus the device can be turned on or off. Importantly, the presence of a relatively small number of charges on the gate electrode alters the flow of a great many charges between the source and drain electrodes. Accordingly, the FET acts as a switch as well as an amplifier.

The SGB integrates another scientific discovery known as organic electronic polymers. This work, which was conducted in the 1970s, focused on the development of doped polyacetylene. Historically conductive polymers can also be traced back to the early 1960s. Conductive polymers have several advantages over other organic conductors with regard to their processability and hence their use is becoming increasingly widespread. The polymers that show the most promise in this area are based on the polythiophene structure. The flexible nature of these polymers allows them to be processed into almost any desired shape or form, making them attractive for the low-cost production of flexible electronic circuits, such as FETs.

The first demonstrated combination of FETs and organic electronic polymers was in the solid-state OTFT developed in 1986 using polythiophene (an organic electronic polymer) as the semi-conducting layer, with a similar device being reported in 1988. The performance of OTFTs in comparison with conventional silicon-based transistors has been considered encouraging and they have already been used in applications in logic circuits or as the driving elements in active matrix displays. Biosensor fabrication based on organic electronics is also well-established, primarily driven by the appealing features offered by these materials such as flexible and adjustable chemical properties, and room temperature operation.

One of the most attractive features of organic electronics is the potential for flexible low-cost fabrication. A common feature of early OTFTs was the use of silicon as the substrate material, and thus since these hybrid devices are not truly all-polymer-based they do not offer all the advantages with respect to fabrication. In the world of sensors, the vast majority of previous scientific research and subsequent technological implementation of organic sensors has involved electrochemically grown films exhibiting performance levels that are, in most cases, inadequate for real applications. Solution-processed polymers, on the other hand, offer the greatest potential for the fabrication of low-cost electronics since they can be easily processed as liquids, unlike the organic crystals and short chain oligomers which are typically vapor deposited. Combining these unique material properties with low-cost techniques, such as ink-jet or reel-to-reel printing, offers the ability to rapidly produce disposable printed electronic circuits.

The first all-polymer printed OTFT was reported in 1994. OTFTs are an exciting class of devices within the organic electronics field. The prospect of low cost organic electronic modules incorporating OTFTs fabricated at low temperatures using low energy techniques is very attractive. Low temperature solution-based processes, such as ink-jet printing, allow for compatibility with flexible substrates, upon which it would be impossible to fabricate conventional electronics. In addition, conducting polymers can be synthesized in a laboratory without using rare or expensive materials.

Other Tests Based on the Biosensor Platform

As discussed above, the architecture of the Biosensor Platform allows the recognition element of the biosensor to be exchanged. Accordingly, the GOX element used to detect glucose in the case of the SGB can be substituted with antibodies specific to SARS-CoV-2, cancer biomarkers, immunological tests, hormones and other biomarkers. The substitute recognition element will generate an electrical current signal that is detected in a manner identical to the SGB. Given the underlying sensing mechanism is unaltered, we believe the technical risk associated with the development of other tests for biomarkers other than glucose is considered to be relatively low.

Performance Testing, Current State of Development and Next Steps

Preliminary Analytical Performance Testing

Regulatory Approval COV2 Test (“COV2T”)

For the COV2T we intend to use the section 564 of the Federal Food, Drug and Cosmetic (FD&C) Act, that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves a novel (new) coronavirus (nCoV) first detected in Wuhan City, Hubei Province, China in 2019 (2019-nCoV). The virus is now named severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), which causes the disease COVID-19.

On the basis of this determination, the Secretary of HHS has subsequently declared that circumstances exist justifying the Emergency Use Authorization (“EUA”) of in vitro diagnostics for the detection and/or diagnosis of COVID-19 (February 4, 2020), personal respiratory protective devices (March 2, 2020), and other medical devices, including alternative products used as medical devices (March 24, 2020), for use during the COVID-19 outbreak pursuant to section 564 of the Act and subject to the terms of any authorization issued under that section.

The criteria for issuance of EUA are the following:

- Serious or life-threatening disease
- Evidence of effectiveness the “may be effective” standard for EUAs provides for a lower level of evidence than the “effectiveness” standard that FDA uses for product approvals. FDA intends to assess the potential effectiveness of a possible EUA product on a case-by-case basis using a risk-benefit analysis. If, based on the totality of the scientific evidence available, it is reasonable to believe that the product may be effective for the specified use, FDA may authorize its emergency use, provided that other statutory criteria for issuing an EUA also are met.

Commercialization

It is the company's intent to introduce and launch the test globally, through assignment of a sublicense and or distributors agreements. The development path will follow the geographical regulatory path, beginning by the North American Markets. The Saliva Glucose Biosensor has been designed and developed to meet the ISO 15197:2013 standard and we intend to seek regulatory approval under the specifications of this standard. The research team at the University of Newcastle, in order to benchmark the performance of the biosensor prototype systems, compared it with the partial requirements of the ISO standard ISO 15197:2013. This standard dictates the analytical standards and performance evaluation of a blood-glucose monitoring system for self-testing in managing diabetes mellitus. The standard dictates that at least 95 % of results for a given system have to be within ± 15 mg/dL at glucose concentrations less than 100 mg/dL and within ± 15 % at glucose concentrations greater than or equal to 100 mg/dL. Artificial saliva was prepared based on the most widely used Fusayama Meyer solution consisting of 11 different glucose concentrations of 0, 0.18, 0.36, 0.9, 1.8, 3.6, 9.01, 18.02, 36.04, 90.1, 180.2 mg/dL. Only the first seven concentrations are clinically relevant in saliva (0 – 9.01 mg/dL)³. However, at this stage of product development we wanted to assess the dynamic range of the biosensor to 20-fold of the upper physiological range (9.01 mg/dL)³. The concentration range of greater than 9.01-180.2 mg/dL is not clinically relevant criteria for glucose in saliva. The results of the 116 prototype biosensors that were assessed for precision and accuracy by implementing the ISO standard. In conclusion, from the 116 devices assessed 110 devices (94.8 %) met the blood glucose ISO standard in relation to the adapted system accuracy (i.e. 95 % of the measured results must fall within ± 15 mg/dL at glucose concentrations less than 100 mg/dL).

We believe the deficiency of the 6 prototype devices that failed to meet the ISO standard is attributable to the previously non-validated manual printing process of the biosensors, rather than a biosensor technology deficiency. Currently the biosensor is in the process of transferring to a quality-controlled pilot production phase, standardizing the automated processes, and characterization procedures which will eliminate such manufacturing deviations in the released biosensor product format. Regardless, 110 prototype sensors in this test performed at a level to allow compliance with the ISO standard. It is important to note that the ISO standard references blood glucose monitors rather than salivary glucose monitors so a direct application of the standard here is not entirely practical.

Manufacturing

The facilities required for the fabrication of these OTFT devices are all in place at the Australian National Fabrication Facility, which we have used for fabrication and testing. These facilities are being extensively used, and we anticipate they can also be used for initial manufacturing and charged under a cost recovery basis.

We have received approval for \$4.7 million (excluding GST/VAT) million Medical Products Priority Grant funding by the Australian Government as contributions towards the establishment of a high-tech manufacturing facility in Australia. Amounts will be paid under this grant upon GBS in achieving certain deliverables.

Inherent in the manufacturing process is a separate calibration process that is batch dependent and ensures analytical performance quality control. Further to this an authenticity validation process verifies that the biosensor is authentic or otherwise flags a device.

Distribution

We intend, assuming the completion of development and regulatory approval, to market and distribute the SGT in the APAC Region. We propose to enter into arrangements with distributors to market and sell the SGB. We have entered into an agreement in principle with a medical affairs commercialization company to drive prelaunch activity with the scope to create awareness and build "share of voice" with local referring physicians, diabetes educators, patient associations, government organizations and general practitioners. We also recently entered into non-binding memoranda of understanding with two large distributors in China, which express our intent to enter into definitive agreements to collaborate on the manufacture, regulatory approval, and distribution and sale of, and the medical affairs, marketing, and identification of strategic opportunities for, the SGB in China. We have engaged L.E.K Consulting to assist in expanding the scope of commercial partners.

Our strategy will depend in part on finding qualified distributors for the marketing and sale of our products. We will work with these distributors to market our products. These distributors typically would sell a variety of other, non-competing products and will be expected to devote certain resources to selling the SGB. We expect to devote suitable time and effort to recruiting and retaining qualified third-party distributors and training them in our technology and product offering. We plan to adopt a multiple channel strategy to balance the marketing and sales efforts.

The Glucose Monitoring Industry

The Self-Monitoring of Blood Glucose

Self-Monitoring of blood glucose is the main approach for glucose monitoring and has been used for over 40 years. Currently, self-monitoring of blood glucose is conducted periodically by the patient using a blood glucose measuring device. Blood glucometers require pricking a finger with a lancet and applying a drop of blood on the test strip. The test strip is then inserted into the device which provides a reading of glucose level in blood. Test strips are supplied by the glucometer manufacturer and are generally device-specific, although generic test strips are also available. There are more than 100 types of blood glucometers currently are commercially available and they differentiate based on size and weight, cost, data storage capacity, test accuracy, blood sample size and screen visibility (users with poor eyesight may prefer larger screens).

Continuous Glucose Monitoring

Continuous glucose monitoring is not an alternative to finger prick self-monitoring of blood glucose. Only one system to date has been deemed of equivalent use “as an aid to monitor the effectiveness of diabetes control” or non-adjunctive use. The procedure is invasive and involves the insertion of a glucose biosensor into the subcutaneous tissue layer or the hypodermis. The biosensor, which measures glucose levels in interstitial fluid, is attached to a transmitter that sends signals to either an insulin pump or a portable meter. These devices are generally worn for about one week and require regular calibration through conventional blood glucose detection, about twice a day. While the accuracy of these devices has been an issue, it has improved in recent years. Continuous glucose monitoring can track a patients’ glucose throughout the day and night, notifying the patient of highs and lows so the person can act. Subcutaneous glucose levels change more slowly than plasma glucose, which can be a restriction to their effectiveness, particularly if glucose levels are changing rapidly. Subcutaneous glucose levels have a time lag compared to blood glucose measurements, and measurements may not always match blood glucose. Continuous glucose monitoring is commonly used in conjunction with continuous subcutaneous insulin infusion, or “CSII,” which involves a patient wearing an insulin pump and infusion set that infuses insulin into the body. Although pumps are currently manually controlled by the patient, continuous glucose monitoring combined with CSII could potentially be used as part of a closed-loop. CSII is generally restricted to Type 1 diabetics, where the need for ongoing insulin infusion is highest. Continuous glucose monitoring is mainly used in a limited proportion of diabetics, particularly those concerned about severe, nocturnal hypoglycemia, pregnant women who require meticulous glucose control or those who may not be able to easily administer a self-monitoring test (e.g., those living in remote or hostile environments). However, continuous glucose monitoring is more expensive than traditional self-monitoring of blood glucose and in many cases is not eligible for reimbursement.

Importance of Glucose Monitoring

One of the main aims of diabetes monitoring and management is to maintain blood glucose levels within a specified target range. Self-monitoring of blood glucose should be part of a regular management plan for patients with diabetes to enable this. Self-monitoring provides information regarding an individual’s dynamic blood glucose profile. This information can help with the appropriate scheduling of food, activity, and medication. It is also required for understanding of the timing of blood glucose variations. Lack of regular self-monitoring predicts hospitalization for diabetes-related complications. Self-monitoring of blood glucose is an essential tool for people with diabetes who are taking insulin or for those who experience fluctuations in their blood glucose levels, especially hypoglycemia. For patients taking insulin and adjusting their dose, self-monitoring is needed for self-management. For others receiving oral medication, profiling glucose trends and the confirmation of high or low blood glucose can be a useful addendum to successful management.

Self-monitoring of blood glucose aids the management of diabetes by:

- facilitating the development of an individualized blood glucose profile, which can then guide health care professionals in treatment planning for an individualized diabetic regimen;
- giving people with diabetes and their families the ability to make appropriate day-to-day treatment choices in diet and physical activity as well as administration of insulin or other agents;
- improving patients' recognition of hypoglycemia or severe hyperglycemia; and
- enhancing patient education and patient empowerment regarding the effects of lifestyle and pharmaceutical intervention on glycemic control.

The role of blood glucose control in preventing the development and progression of complications has been proven in both type 1 and type 2 diabetes, with an especially strong relationship between intensive blood glucose control and complications such as neuropathy (affecting limbs) and diabetic retinopathy (leading to blindness).

Over time, glucose measurements are expected to provide the patient and their health care professionals with the information and insights required to determine the best management strategy for diabetes, potentially minimizing the fluctuations in their glucose levels and resulting in better health outcomes.

The role of blood glucose monitoring and control in preventing the development and progression of diabetes complications has been well established. Studies show that those who properly monitored blood glucose levels had better health outcomes (such as reduced complications of diabetes) compared to those who did not.

For a person with diabetes, however, this daily process is not only painful but can be exhausting, disruptive, frustrating, frightening and consuming, which often leads to poor compliance and poor health outcomes. People with diabetes have reported that stigma is a significant concern to them. This causes tension and anxiety and, because the procedure is perceived as inconvenient and difficult, leads to suboptimal monitoring and poor adherence. Many people with diabetes do not test as often as clinically recommended, increasing the risk of complications.

Technology License Agreement

On June 23, 2020, we entered into a certain Technology License Agreement, or the "License Agreement," with Life Science Biosensor Diagnostics Pty Ltd, ("LSBD" or "Licensor"). The Licensor owns 42.6% of our outstanding common stock (by voting rights) as of June 30, 2021.

The License Agreement sets forth our contractual rights and responsibilities relating to the Licensed Products. The "Licensed Products" include: (i) a biosensor strip for antibodies against SARS-CoV-2; (ii) a proprietary smartphone application for the purpose reading, storing, analyzing and providing patient support programs for any one or more of the Indicators for the purpose of measuring the amount or concentration of immunoglobulins (IgG, IgM, IgA) specific to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2); and/or (iii) a dedicated sensor strip reading device for any one or more of the Indicators for the purpose of measuring the amount or concentration of immunoglobulins (IgG, IgM, IgA) specific to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

An "Authorized Supplier" includes us, the Licensor, any of our affiliates or any affiliates of the Licensor, or any third party manufacturer and/or reseller that the Licensor has expressly identified or approved in advance in writing for the purpose of quality control for the supply of Licensed Products to us.

Pursuant to the License Agreement, the Licensor granted to us an exclusive license to the Licensor's proprietary rights to the biosensor technology used in the Licensed Products, worldwide and solely to:

- act as the authorized party for the purpose of prosecuting the application of, and obtaining any, regulatory approval for the Licensed Product, including being authorized to prosecute the approval for an investigational device required for the purpose of carrying out clinical studies;
- manufacture, promote, market, import, offer, sell and distribute the Licensed Products;
- provide reasonable customer support services on the use of the Licensed Products to end users of, and health care practitioners referring end users to, the Licensed Products;
- use the Licensed Products only for the purposes identified and permitted pursuant to regulatory approval; and
- collect data acquired from the Licensed Products.

We are required to collect and anonymize demographic information about the end users of the Licensed Products and data acquired from the Licensed Products. While the anonymized data will be owned by the Licensor, we will own during the term of the License Agreement the personally identifiable data, including health data, collected by us. In addition, the Licensor will provide us with certain of the data acquired from the Licensed Products. The demographic information and personally identifiable information will be used, following patient consent, as a disease management tool to offer patients value-added services, i.e., personalized education services for lifestyle, diet and glucose management. These services will be in accordance with the applicable local medical codes and regulatory environment. The use of such consensual information will be in accordance with privacy laws of the relevant countries and territories.

The license is non-transferable, non-assignable and non-sublicensable, except that the Licensor will in good faith consider any request by us for any sublicense.

Commencing after the receipt of regulatory approval in a jurisdiction, and the earning of revenue we will be required to pay the Licensor a minimum royalty fee with respect to such jurisdiction for each year, or the "Minimum Royalty," in four equal quarterly installments. The Minimum Royalty will be 13% of the projected net sales in such jurisdiction for each such year. The projected net sales will be an amount mutually agreed between us and the Licensor for the first such year. For each ensuing year after the first year, the projected net sales will be the number of Licensed Products sold in such jurisdiction in the prior year, as adjusted for the mutually agreed expected market growth. In addition to the expected market growth, there will be an additional growth rate percentage of 7% for each year through the tenth year. In the event of a dispute between us and the Licensor regarding the determination of the expected market growth or the additional growth percentage, the License Agreement provides for resolution by an independent third party. At the end of each quarter, if the quarterly installment of the Minimum Royalty is less than 13% of the actual net sales of Licensed Products in such jurisdiction for such quarter, or the "Actual Royalty," we will pay Licensor the difference between the quarterly installment of the Minimum Royalty and the Actual Royalty. The royalty fee rate will be reduced from 13% to 3% upon the expiration of the patent portfolio covered by the License Agreement.

As between us and the Licensor, the Licensor solely owns all right, title and interest to, among other items of intellectual property, the biosensor technology (including any improvements made to the biosensor technology by us), the anonymized data collected by us and any other technology of the Licensor, and all derivations based on, and all proprietary rights in, the foregoing. The Licensor will have the right to decide whether to protect or enforce, and the right to control any action relating to the protection and enforcement of, any of the foregoing intellectual property and proprietary rights.

There is no set expiration date for the License Agreement. However, the exclusivity of the license granted under the License Agreement runs until the expiration of the patent portfolio covered by the License Agreement, which is currently until 2033. We expect that the patent portfolio will be extended as new patents are created throughout product development, thereby extending the exclusivity of the License Agreement. For instance, we expect to seek additional patents in connection with the development of the Prostate Specific Antigen test, the Peanut Kernel Allergen test and the Luteinizing Hormone test. The License Agreement may be terminated by us in the event of a material breach by the Licensor, if the Licensor does not cure the breach within 30 days after receiving notice of the breach; or in the event the Licensor discontinues its business operations or in the case of certain events related to insolvency or bankruptcy. The License Agreement also may be terminated by us at any time after the tenth anniversary of the License Agreement upon 180 days' prior written notice.

On March 31, 2021, the Company, entered into an Option Agreement with LSBD and BiosensX (North America) Inc. ("BIOX"). Under the terms of this Option Agreement, LSBD granted to the Company an exclusive option (the "Option") to purchase an exclusive license to use, make, sell and offer to sell products under the intellectual property rights in connection with the Biosensor technology the glucose/diabetes management field in the United States, Mexico and Canada (the "NA Territory"). The Company is entitled to exercise this Option at any time during the 2-year term from the effective date of the Option Agreement by paying the option fee in the amount of \$5 million to LSBD at the time of the option exercise. Upon such exercise, (i) LSBD and BIOX will promptly terminate their respective agreement with respect to the NA Territory, and (ii) LSBD and the Company will promptly enter into a license agreement pursuant to which LSBD will grant an exclusive license (with the right to sublicense) to the Company, substantially on the same set of terms as the LSBD-BIOX license agreement currently in place, provided that the license agreement between LSBD and the Company will also contain a commercialization milestone payment to the LSBD for the equivalent of 5 years' of royalties based upon agreed maintainable sales due 90 days from the end of the first royalty year. The terms and provisions of the foregoing transaction have been reviewed and approved by the Company's Board of Directors and the Audit Committee of the Board.

Intellectual Property

Our business depends on the proprietary biosensor technologies licensed by us from the Licensor. The Licensor has secured and continues to pursue intellectual property rights related to this technology in China, the United States and other countries. The original patent application, which claims a priority date of March 2012, has been granted in the United States (9,766,199) and China (ZL201380022888.2). A second international patent application (PCT/AU2016/050555) claiming iterations to the device design has been filed with a priority date of June 2016 and will soon enter national phase in certain jurisdictions, and further patent applications are in preparation. The patents protect the following technological claims of the SGB: the architecture of a biofunctional organic thin film transistor device comprising a gate electrode, a dielectric layer, a partially-organic semiconducting layer, a source electrode, a drain electrode, a substrate and an enzyme; the method for producing the organic thin film transistor device; and the method for determining the concentration of a compound in a sample by interpreting the amperometric signals generated by the device. The Chinese and the United States patent belong to the same patent family, originating from the Australian patent. As such, all of the patents relate to identical technology claims.

We believe that the Licensor intends to aggressively prosecute these patent applications and file further applications, as appropriate, to protect the proprietary biosensor technologies, including improvements thereon, in the United States as well as in the APAC Region, and to take any necessary action to maintain and enforce its patent and other intellectual property rights. There can be no assurance, however, that the Licensor will take such actions, and under the License Agreement, we have no right to compel them to do so. If the Licensor elects not to protect or enforce its intellectual property rights, we would be permitted take action to protect or enforce these rights in the APAC Region, but any such action would be at our cost and expense.

We intend to vigorously protect our intellectual property rights in any technologies owned by us through patents and copyrights, as available through registration in the United States and internationally. We also will rely upon trade secrets, know-how, and continuing technological innovation to develop and maintain our competitive position. We intend to protect any of our proprietary rights through a variety of methods, including confidentiality agreements and/or proprietary information agreements with suppliers, employees, consultants, independent contractors and other entities who may have access to proprietary information. We will generally require employees to assign patents and other intellectual property to us as a condition of employment with us. All of our consulting agreements will pre-emptively assign to us all new and improved intellectual property that arise during the term of the agreement. In addition, we may license additional technologies from the Licensor or third parties. Prior to any further acquisition or licensing of technology from a third party, we will evaluate the existing proprietary rights, our ability to obtain and protect these rights, and the likelihood or possibility of infringement upon competing rights of others.

The issuance of a patent does not ensure that it is valid or enforceable. The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the earliest date of filing a non-provisional patent application. In the United States, a patent's term may be shortened if a patent is terminally disclaimed over another patent or as a result of delays in patent prosecution by the patentee, and a patent's term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the United States Patent and Trademark Office in granting a patent.

We conduct our business using the licensed trademark "Glucose Biosensor" and our logo, as well as domain names incorporating either or both of these trademarks. Our trademarks are not registered. We own the domain name *glucosebiosensor.com*.

Competition

The medical device industry is highly competitive, subject to rapid change and significantly affected by new product introductions and other activities of industry participants. We face potential competition from major medical device companies worldwide, many of which have longer, more established operating histories, and significantly greater financial, technical, marketing, sales, distribution, and other resources. Our overall competitive position is dependent upon a number of factors, including product performance and reliability, connectivity, manufacturing cost, and customer support.

The glucose monitoring industry currently is dominated by blood glucometers that require pricking a finger with a lancet and applying a drop of blood on a test strip. Our major competitors for glucose testing solutions include Bayer, Abbott, and Roche.

Government Regulation

We operate in a highly regulated industry. Our present and future business has been, and will continue to be, subject to a variety of laws globally regarding quality, safety and efficacy, and governing, among other things, clinical evaluations, marketing authorization, commercial sales and distribution of our products.

Internationally, various regulatory bodies monitor and supervise the administration of pharmaceutical products, as well as medical devices and equipment. Their primary responsibilities include evaluating, registering and approving new drugs, generic drugs and imported drugs; approving and issuing permits for the manufacture, export and import of pharmaceutical products and medical appliances; approving the establishment of enterprises for pharmaceutical manufacture and distribution; formulating administrative rules and policies concerning the supervision and administration of food, cosmetics and pharmaceuticals; and handling significant accidents involving these products.

We also will be subject to numerous post-marketing regulatory requirements, which may include labeling regulations and medical device reporting regulations, and which may require us to report to different regulatory agencies if our device causes or contributes to a death or serious injury, or malfunctions in a way that would likely cause or contribute to a death or serious injury. We may be subject to further regulations in the areas of import and export restrictions and tariff regulations, duties and tax requirements. In addition, these regulatory requirements may change in the future.

Employees

In the past, we have utilized for our benefit certain employees of the Licensor, our largest stockholder. We have not incurred or accrued any financial or other obligations other than certain shared corporate overhead as required in connection with this utilization. We have reimbursed the Licensor for any costs the Licensor incurs on our behalf.

Recently, in anticipation of product commercialization, we have expanded our team. We currently have seven full time employees and two part-time employees. We also rely on the services of contractors, collaborators and consultants. We have assembled an outstanding team of 14 people, including our 9 employees, our scientific advisory board and personnel at the University of Newcastle through a collaboration with the institution, to execute on our mission to create next generation non-invasive diagnostic tools to help patients suffering with diabetes. From time to time, we also contract for various administrative and other services from our largest stockholder, the Licensor, as required. Our employees, including our management, have extensive experience in the research, development and commercialization of life science assets and are leaders in their respective fields.

Our team, including our employees, contractors and collaborators, comprises multiple cross-functional units, including strategy, project management, technical engineering, manufacturing and supply chain, and quality assurance, legal and compliance, regulatory affairs, clinical affairs, product management & marketing, systems engineering, human resources, IT, investor relations, and finance. We believe our team collectively possesses industry leading capabilities and positions us to build a strong life science company focused on developing next generation non-invasive diagnostic tools for the tens of millions of diabetes patients worldwide.

Initial public offering

On December 28, 2020, the Company closed its initial public offering (“IPO”) and sold 1,270,589 units, consisting of (a) one share of the Company’s common stock (or, at the purchaser’s election, one share of Series B Convertible Preferred Stock), (b) one Series A warrant (the “Series A Warrants”) to purchase one share of the Company’s common stock at an exercise price equal to \$8.50 per share, exercisable until the fifth anniversary of the issuance date, and (c) one Series B warrant (the “Series B Warrants”) to purchase one share of the Company’s common stock at an exercise price equal to \$17.00 per share, exercisable until the fifth anniversary of the issuance date and subject to certain adjustment and cashless exercise provisions. The public offering price of the shares sold in the IPO was \$17.00 per unit. In aggregate, the units issued in the offering generated \$17,732,448 in net proceeds, which amount is net of \$1,714,001 in underwriters’ discount and commissions, and \$2,153,564 in offering costs. Offering costs include underwriters’ warrants to acquire up to 63,529 shares with an exercise price of \$18.70 per share, exercisable until the fifth anniversary of the issuance date. The Company also issued to the underwriter an option, exercisable one or more times in whole or in part to purchase up to 190,588 additional shares of common stock and/or Series A Warrants to purchase up to an aggregate of 190,588 shares of common stock and/or Series B Warrants to purchase up to an aggregate of 190,588 shares of common stock, in any combinations thereof, from us at the public offering price per security, less the underwriting discounts and commissions, for 45 days after the date of the IPO to cover over-allotments, if any (the “Over-Allotment Option”).

Upon the closing of the IPO, all shares of preferred stock then outstanding were automatically converted into 2,810,190 shares of common stock, and all convertible notes then outstanding were automatically converted into 710,548 shares of common stock.

Pre-IPO preferred shareholders were issued warrants following the Company’s completed IPO, that allow the holders to acquire 2,736,675 shares of common stock at the IPO price during year two through to year three following the completion of the IPO. At exercise date, the shareholder must hold, for each warrant to be exercised, the underlying common share to exercise the warrant. The warrants are not transferable and apply to the number of shares that were subscribed for.

Access to Information

Our website is at www.gbs.inc we make available, free of charge, on our corporate website, our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), as soon as reasonably practicable after they are electronically filed with the Securities and Exchange Commission (“SEC”). The SEC maintains an internet site that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC at www.sec.gov. Information contained on our website does not, and shall not be deemed to, constitute part of this Annual Report on Form 10-K. Our reference to the URL for our website is intended to be an inactive textual reference only.

ITEM 1A. RISK FACTORS.

Our business is subject to a number of risks. You should carefully consider the following risk factors, together with all of the other information included or incorporated by reference in this report, before you decide whether to purchase our common stock. These factors are not intended to represent a complete list of the general or specific risks that may affect us. It should be recognized that other risks may be significant, presently or in the future, and the risks set forth below may affect us to a greater extent than indicated. If any of the following risks occur, our business, financial condition and results of operations could be materially adversely affected. In such case, the trading price of our common stock could decline, and you may lose all or part of your investment.

Forward-looking statements in this document and those we make from time to time through our senior management are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements concerning the expected future revenue or earnings or concerning projected plans, performance, or development of products and services, as well as other estimates related to future operations are necessarily only estimates of future results. We cannot assure you that actual results will not materially differ from expectations. Forward-looking statements represent our current expectations and are inherently uncertain. We do not undertake any obligation to update forward-looking statements.

Summary of Risk Factors

The summary below provides a non-exhaustive overview of the risks that if realized could materially harm our business, prospects, operating results and financial condition. This summary is qualified by reference to the full set of risk factors set forth in this Item.

- COVID-19 may impact our operations.
- We have incurred significant losses since inception and may not be able to achieve significant revenues or profitability.
- Given our lack of revenue and our negative cash flow, we may need to raise additional capital, which may be unavailable to us or, even if consummated, may cause dilution or place significant restrictions on our ability to operate.
- The License Agreement with the Licensor, our largest stockholder, which covers the license of the core technology used in our products, contains significant risks that may threaten our viability or otherwise have a material adverse effect on us and our business, assets and its prospects.
- Neither we nor the Licensor have yet launched the COV2T or the SGT and the ability to do so will depend on the acceptance of the COV2T and/or the SGT in the Global healthcare market.
- If the COV2T and/or SGT fails to satisfy current or future customer requirements, we may be required to make significant expenditures to redesign the product candidate, and we may have insufficient resources to do so.
- Initially, we expect to derive a significant proportion of our revenues from the COV2 test (“COV2T”) and the underlying Biosensor Platform technology.
- We have yet to finalize the manufacturing plan for the production of the COV2T nor the SGT and its components on a mass market commercial scale, and may be dependent upon third-party manufacturers and suppliers, making us vulnerable to contractual relationships and market forces, supply shortages and problems and price fluctuations, which could harm our business.
- If third-party payors do not provide coverage and reimbursement for the use of the COV2T and/or SGT, our business and prospects may be negatively impacted.
- Non-United States governments often impose strict price controls, which may adversely affect our future profitability.

- The COV2T and/or SGT, including its software and systems, may contain undetected errors, which could limit our ability to provide our products and services and diminish the attractiveness of our service offerings.
- If we are not able to attract and retain highly skilled managerial, scientific and technical personnel, we may not be able to implement our business model successfully.
- Product liability suits, whether or not meritorious, could be brought against us due to an alleged defective product or for the misuse of the COV2T and/or SGT. These suits could result in expensive and time-consuming litigation, payment of substantial damages, and an increase in our insurance rates.
- We are party to agreements pursuant to which we may be required to make payments to certain of our affiliates, which may reduce our cash flow and profits.
- The regulatory approval process which we may be required to navigate may be expensive, time-consuming, and uncertain and may prevent us from obtaining clearance for the product launch of the SGT or our any future product.
- Clinical data obtained subsequent to the implementation of the clinical evidence module may not meet the required objectives, which could delay, limit or prevent additional regulatory approval.
- We may be unable to complete required clinical evaluations, or we may experience significant delays in completing such clinical evaluations, which could prevent or significantly delay our targeted product launch timeframe and impair our viability and business plan.
- We are subject to the risk of reliance on third parties to conduct our clinical evaluation work.
- We depend on intellectual property licensed from the Licensor, and any absence of legal effect of the license or dispute over the license would significantly harm our business.
- The Licensor has limited foreign intellectual property rights and may not be able to protect its intellectual property rights.
- We and the Licensor may be subject to claims challenging the invention of the intellectual property that we license from the Licensor.
- We face intense competition in the self-monitoring of glucose market, particularly blood-based products, and as a result we may be unable to effectively compete in our industry.
- The medical device and other medical product industries in the APAC Region generally are highly regulated and such regulations are subject to change.
- We are subject to laws and regulations governing business conduct, which will require us to develop and implement costly compliance programs.
- Our customers for the Saliva Glucose Test initially may be concentrated in China; in which case we may be susceptible to risks specifically associated with business activities in China.
- We may not be able to satisfy the continued listing requirements of the NASDAQ Global Market in order to maintain the listing of our common stock.
- There is no public market for the Series B Convertible Preferred Stock and an active trading market for the same is not expected to develop.

- LSBD, our largest stockholder, may exert significant influence over our affairs, including the outcome of matters requiring stockholder approval.

- We are obligated to develop and maintain a system of effective internal control over financial reporting. We may not complete our analysis of our internal control over financial reporting in a timely manner, or these internal controls may not be determined to be effective, which may harm investor confidence in our company and, as a result, the value of our common stock.

- We will incur increased costs as a result of operating as a public company and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices. Moreover, our ability to comply with all applicable laws, rules and regulations is uncertain given our management's relative inexperience with operating United States public companies.

Risks Related to Our Business

COVID-19 may impact our operations.

On January 30, 2020, the International Health Regulations Emergency Committee of the World Health Organization (WHO) declared the COVID-19 coronavirus outbreak a public health emergency of international concern and on March 10, 2020, declared it to be a pandemic. Actions taken around the world to help mitigate the spread of the coronavirus include restrictions on travel, and quarantines in certain areas, and forced closures for certain types of public places and businesses. The COVID-19 coronavirus and actions taken to mitigate it have had and are expected to continue to have an adverse impact on the economies and financial markets of many countries, including the geographical area in which we operate. Although COVID-19 has begun to show signs of stabilization in certain regions, the potential impact brought by and the duration of the COVID-19 outbreak is difficult to assess or predict and the full impact of the virus on our operations will depend on many factors beyond our control. For instance, our business operations may be adversely affected if global economies continue to be affected by COVID-19. While it is unknown how long these conditions will last and what the complete financial effect will be to our company, we are closely monitoring its impact on us. Our business, results of operations, financial conditions and prospects could be materially adversely affected to the extent that COVID-19 harms the global economy in general, and the trading price of our stock may be adversely affected. In addition, the Company expects the impact of COVID-19 on the Company's capital and financial resources to be minimal. Its ability to raise money from the capital market by issuing equity may be adversely affected by the pandemic, and the cost of capital will likely be higher. The Company does not expect any material impairments as a result of the impact by COVID-19 pandemic. While the Company has not experienced challenges in implementing its business plans in the near-term, or requiring material expenditures to do so, if the pandemic continues and/or there is a second wave of COVID-19, the Company is likely to need more expenditures to sustain its operations.

We are subject to the risks associated with new businesses.

We were formed in December 2016 as a new business with a plan to commercialize our licensed technology. Our limited operating history may not be adequate to enable you to fully assess our ability to develop and market the SGT and other tests based on the Biosensor Platform, achieve market acceptance of the COV2 Test ("COV2T") and/or SGT and such other tests and respond to competition. Our efforts to date have related to the organization and formation of our company, strategic planning, product research and development and preparation for commencing regulatory trials and have depended on support from the Licensor and its affiliates. We have not yet generated revenue, and we cannot guarantee we will ever be able to generate revenues. Therefore, we are, and expect for the foreseeable future to be, subject to all the risks and uncertainties, inherent in a new business focused on the development and sale of new medical devices and related software applications. As a result, we may be unable to further develop, obtain regulatory approval for, manufacture, market, sell and derive revenues from the COV2 Test ("COV2T") and/or SGT and the other products in our pipeline based on the Biosensor Platform, and our inability to do so would materially and adversely impact our viability. In addition, we still must optimize many functions necessary to operate a business, including expanding our managerial, personnel and administrative structure, continuing product research and development, and assessing and commencing our marketing activities.

Accordingly, you should consider our prospects in light of the costs, uncertainties, delays and difficulties frequently encountered by companies that have not yet commercialized their products or services, particularly those in the medical device and digital health fields. In particular, potential investors should consider that there is a significant risk that we will not be able to:

- implement or execute our current business plan, or that our business plan is sound;
- maintain our management team and Board of Directors;
- determine that the technologies that have been developed are commercially viable;
- attract, enter into or maintain contracts with, and retain customers; and
- raise any necessary additional funds in the capital markets or otherwise to effectuate our business plan.

In the event that we do not successfully address these risks, our business, prospects, financial condition, and results of operations could be materially and adversely affected.

We have incurred significant losses since inception and may not be able to achieve significant revenues or profitability.

Since our inception, we have engaged primarily in development activities. We have financed our operations primarily through financing from private capital raising and support from our largest stockholder, and have incurred losses since inception, including a net loss of \$5,020,383 for the fiscal year ended June 30, 2018, a net loss of \$7,336,686 for the fiscal year ended June 30, 2019, a net loss of \$3,163,776 for the fiscal year ended June 30, 2020 and a net loss of \$7,037,286 for the fiscal year ended June 30, 2021. We do not know whether or when we will become profitable. Our ability to generate revenue and achieve profitability depends upon our ability, alone or with others, to complete the development process of our products, including regulatory approvals, and thereafter achieve substantial acceptance in the marketplace for our products. We may be unable to achieve any or all of these goals.

Given our lack of revenue and our negative cash flow, we may need to raise additional capital, which may be unavailable to us or, even if consummated, may cause dilution or place significant restrictions on our ability to operate.

We believe we have sufficient capital resources to enable us to continue to implement our business plan and remain in operation for at least the next 15 months from the date this report. We cannot yet forecast revenues, if at all, and our revenues will not immediately be sufficient to finance our ongoing operations. In addition, available resources may be consumed more rapidly than currently anticipated, and there can be no assurance that we will be successful in developing the COV2 Test (“COV2T”) and/or SGT and generating sufficient revenue in the timeframe set forth above, or at all. We may also need additional funding for developing new products and services and for additional sales, marketing and promotional activities. Accordingly, we may need to seek additional equity or debt financing earlier than anticipated to provide the capital required to maintain or expand our operations. We may raise additional capital through sales of equity securities or the incurrence of debt. If such financing is not available on satisfactory terms, or is not available at all, we may be required to delay, scale back or eliminate the development of business opportunities and our operations and financial condition may be materially adversely affected.

The License Agreement with the Licensor, our largest stockholder, which covers the license of the core technology used in our products, contains significant risks that may threaten our viability or otherwise have a material adverse effect on us and our business, assets and its prospects.

Under the terms of the Technology License Agreement executed by the Company and LSBDD dated as of June 23, 2020, the Company is the global licensee and intends to introduce and launch COV2 diagnostic tests across the US, Europe, APAC and the rest of the world through appropriately qualified distributors and includes the terms and related risks set forth below.

The Amended and Restated License Agreement, dated September 12, 2019, which amends and restates all previous license agreements (the “SGT License Agreement”) is limited to the APAC Region and includes the terms and related risks set forth below. We have no contractual rights to the intellectual property covered in the License Agreement other than as expressly set forth therein. Our plans, business, prospects and viability are substantially dependent on that intellectual property and subject to the limitations relating thereto as set forth in the License Agreement:

- The SGT license granted to us is limited in territorial scope. The Licensor, which owns a 42.6% (by voting rights) of our common stock as of June 30, 2021, granted us a license to its proprietary rights in the biosensor technology used in the Licensed Products solely in the APAC Region, and primarily to act as authorized party for obtaining regulatory approval and to manufacture (subject to being approved as an Authorized Supplier by the Licensor) for use in the APAC Region, and to promote, market, import, offer sell and distribute the Licensed Products in the APAC Region. We may not exploit or seek to exploit any rights in respect of the Licensed Product outside of the APAC Region through any means, including digitally or online where the end user is not physically resident in the APAC Region. Accordingly, to the extent that such users are prohibited, we will be unable to realize any commercialization from such users and ensure that such users do not do business with us, even as such commercialization and business might be appropriate, related, synergistic or enhanced by our operations. In addition, we may be responsible for costs and other liabilities that might arise to the extent that users outside the APAC Region obtain such access and may incur costs to comply with these prohibitions. Further, the non-coverage of digital or online use for users not physically in the APAC Region may constitute a material limitation on our ability to freely conduct business digitally, online or through any other medium that may reach outside of the APAC Region. This limitation may have a material adverse effect on our marketing, sales, operational and other business efforts.
- After the receipt of regulatory approval in a jurisdiction, we may be required to pay the Minimum Royalty with respect to such jurisdiction regardless of the actual amount of sales by us of Licensed Products. Accordingly, although the Minimum Royalty is based on our projected sales in each such jurisdiction, and although the determination of the Minimum Royalty is subject to agreement between us and the Licensor as to certain parameters, as described elsewhere in this prospectus, with disputes generally resolved by an independent third party, we could be obligated to pay royalties even though we have generated no or limited revenue. Such payments could materially and adversely affect our profitability and could limit our investment in our business.

- The Licensed Products include only products that are supplied by an Authorized Supplier. Accordingly, we will not have unfettered right to select our suppliers, regardless of whether an unauthorized supplier could provide products on better pricing, delivery, quality or other terms, thus potentially materially and adversely impacting those aspects of our business, economies, profitability and prospects.
- We are required to collect and anonymize demographic information about the end users of the Licensed Products, as well as data acquired from the Licensed Products. The data collection and retention may be expensive in cost, resources, legal and regulatory compliance and other ways, none of which costs can be quantified at this time. Further, changing regulations with respect to medical and similar such data may make such compliance beyond the scope of our capabilities. Any failure to comply may result in financial liability, as well as reputational harm.
- The license is non-transferable, non-assignable and non-sublicensable, except that the Licensor will in good faith consider any request by us for any sublicense. The Licensor is not obligated to agree to any such sub-license. These restrictions may limit our flexibility to structure our operations in the most advantageous manner.
- We must manufacture, promote, market, import, offer, sell, distribute and supply the Licensed Products in accordance with certain distribution requirements set forth in the License Agreement. For instance, we may not package the Licensed Products with other products, and we may deliver them only as supplied by an Authorized Supplier. Accordingly, the limitations imposed by the License Agreement may impact our ability to pursue certain marketing strategies and distribution channels, which may have a material adverse effect on us and our business, assets and prospects.
- The Licensor may require any change to any Licensed Product by any Authorized Supplier and may make any change to any sales or promotional literature made available by the Licensor, provided that such changes do not affect any regulatory approvals we obtain. This right of the Licensor may create material expense for us, may be practically difficult to accomplish and may cause relationship, reputational and other adverse harm to us, our business and our prospects, without our having any control over these changes. Further, the Licensor is not liable for any of the costs to us of such changes.
- We must file for, prosecute the application for, and obtain all regulatory approvals for each of the Licensed Products and all legal permits necessary for promoting, marketing, offering or selling each Licensed Product. The regulatory approval process can be expensive and time consuming, and there can be no assurances that we will be able to obtain or maintain any or all required permits.
- Except with respect to the Licensor's ownership of all intellectual property rights in respect of the licensed property and the non-infringement by our exercise of those rights, the Licensor provides no, and disclaims all, representations, warranties or covenants relating to the licensed intellectual property or any other matters under the License Agreement and in particular disclaims any fitness of the property for any purpose. These provisions limit our recourse in the event that the licensed intellectual property is flawed, defective, inadequate, incomplete, uncommercial, wrongly described or otherwise not useful for our purposes. We have not independently verified any of the technical, scientific, commercial, legal, medical or other circumstances or nature of the licensed intellectual property and therefore there can be no assurances that any of the foregoing risks have been reduced or eliminated. These provisions represent a significant risk of a material adverse impact on us, our business and our prospects.

Neither we nor the Licensor have yet launched the COV2T or the SGT and the ability to do so will depend on the acceptance of the COV2T and/or the SGT in the Global healthcare market.

Neither we nor the Licensor has yet launched the COV2T nor the SGT and neither has received regulatory approvals in any country or territory. We are faced with the risk that the COV2 Test and/or the SGT will be accepted in their respective jurisdictions over competing products and that we will be unable to enter the marketplace or compete effectively. Factors that could affect our ability to establish the COV2T and/or the SGT or any future diagnostic test based on the Biosensor Platform include:

- sales of the COV2T and/or the SGT across their respective jurisdictions may be limited due to the complex nature of the healthcare system in each country and territory in the region, low average personal income, lack of patient cost reimbursement and pricing controls
- the development of products or devices which could result in a shift of customer preferences away from our device and services and significantly decrease revenue;
- the increased use of improved diabetes drugs that could encourage certain diabetics to test less often, resulting in less usage of self-monitoring (saliva-based, blood-based or otherwise) test device for certain types of diabetics;
- the challenges of developing (or acquiring externally developed) technology solutions that are adequate and competitive in meeting the requirements of next-generation design challenges;
- the significant number of current competitors in the glucose monitoring market who have significantly greater brand recognition and more recognizable trademarks and who have established relationships with diabetes healthcare providers and payors; and
- intense competition to attract acquisition targets, which may make it more difficult for us to acquire companies or technologies at an acceptable price or at all.

We cannot assure you that the COV2T and/or SGT or any future diagnostic test based on the Biosensor Platform will gain market acceptance. If the market for the COV2T and/or SGT or any future test fails to develop or develops more slowly than expected, or if any of the technology and standards supported by us do not achieve or sustain market acceptance, our business and operating results would be materially and adversely affected.

We cannot accurately predict the volume or timing of any sales, making the timing of any revenues difficult to predict.

We may be faced with lengthy and unpredictable customer evaluation and approval processes associated with the COV2T and/or SGT. Consequently, we may incur substantial expenses and devote significant management effort and expense in developing customer adoption of the COV2T and/or SGT, which may not result in revenue generation. We must also obtain regulatory approvals of the COV2T and/or SGT in each respective jurisdiction, which is subject to risk and potential delays, and may actually occur. The same risks apply to other tests we may develop based on the Biosensor Platform. As such, we cannot accurately predict the volume, if any, or timing of any future sales.

If the COV2T and/or SGT fails to satisfy current or future customer requirements, we may be required to make significant expenditures to redesign the product candidate, and we may have insufficient resources to do so.

The COV2T and/or SGT is being designed to address an existing marketplace and must comply with current and evolving customer requirements in order to gain market acceptance. There is a risk that the COV2T and/or SGT will not meet anticipated customer requirements or desires. If we are required to redesign our products to address customer demands or otherwise modify our business model, we may incur significant unanticipated expenses and losses, and we may be left with insufficient resources to engage in such activities. If we are unable to redesign our products, develop new products or modify our business model to meet customer desires or any other customer requirements that may emerge, our operating results would be materially adversely affected, and our business might fail.

Initially, we expect to derive a significant proportion of our revenues from the COV2 test (“COV2T”) and the underlying Biosensor Platform technology.

We expect to derive substantially all of our revenues from sales of products derived from the Biosensor Platform technology, which we license from the Licensor. Our initial product utilizing this technology is the COV2 Test. As such, any factor adversely affecting sales of the COV2T, including the product development and release cycles, regulatory issues, market acceptance, product competition, performance and reliability, reputation, price competition and economic and market conditions, would likely harm our operating results. We may be unable to fully develop the COV2 Test or other products utilizing our technology, which may lead to the failure of our business. Moreover, in spite of our efforts related to the registration of our technology, if intellectual property protection is not available for the Biosensor Platform technology, the viability of the COV2 test and any other products that may be derived from such technology would likely be adversely impacted to a significant degree, which would materially impair our prospects.

We have yet to finalize the manufacturing plan for the production of the COV2T nor the SGT and its components on a mass market commercial scale, and may be dependent upon third-party manufacturers and suppliers, making us vulnerable to contractual relationships and market forces, supply shortages and problems and price fluctuations, which could harm our business.

While we are using the facilities of Australian National Fabrication Facility to manufacture the COV2T and SGB for clinical evaluation, we have yet to finalize the manufacturing plan for the production of the COV2T nor SGT and its components on a mass market commercial scale. We presently do not possess the manufacturing and processing capacity to meet the production requirements of consumer demand in a timely manner. Accordingly, we may rely on outsourcing the manufacturing of the COV2T and/or SGT or its components. Our capacity to conduct clinical evaluation and launch our products in the market will depend in part on our ability or the ability of third-party manufacturers to provide our products on a large scale, at a competitive cost and in accordance with regulatory requirements. We cannot guarantee that we or our third-party manufacturers or suppliers will be able to provide the COV2T and/or SGT and its components in mass-market quantities in a timely or cost-effective manner, or at all. Delays in providing or increasing production or processing capacity could result in additional expense or delays in our clinical evaluation, regulatory submissions and the market launch of our products. In addition, we or our third-party manufacturers or suppliers could make errors that could adversely affect the efficacy or safety of the COV2T and/or SGT or cause delays in shipment. Any third-party party manufacturers or suppliers may encounter problems for a variety of reasons, including, for example, failure to follow specific protocols and procedures, failure to comply with applicable legal and regulatory requirements, equipment malfunction and environmental factors, failure to properly conduct their own business affairs, and infringement of third-party intellectual property rights, any of which could delay or impede their ability to meet our requirements. Reliance on these third-party manufacturers or suppliers also subjects us to other risks where:

- we may have difficulty locating and qualifying alternative manufacturers or suppliers;
- switching manufacturers or suppliers may require product redesign and possibly submission to regulatory bodies, which could significantly impede or delay our commercial activities;
- sole-source manufacturers or suppliers could fail to supply the COV2T and/or SGT or components of the COV2T and/or SGT; and
- manufacturers or suppliers could encounter financial or other business hardships unrelated to us, interfering with their fulfillment of our orders and requirements.

We may not be able to quickly establish additional or alternative manufacturers or suppliers if necessary, in part because we may need to undertake additional activities to establish such manufacturers or suppliers as required by the regulatory approval process. We potentially will rely on certain single-source manufacturers or suppliers, and to the extent we do so, these risks will be intensified. Any interruption or delay in obtaining products or components from our third-party manufacturers or suppliers, or shortages of products or components, could impair our ability to meet the demand of our customers and cause them to switch to competing products.

We expect to rely in part on third-party distributors to effectively distribute our products.

We will depend in part on qualified distributors for the marketing and selling of our products. We will depend on these distributors' efforts to market our products, yet we will be unable to control their efforts completely. While we recently entered into non-binding memoranda of understanding with two large distributors in China for the SGT, we have not yet executed any definitive distribution agreements in this regard and there can be no assurances that suitable distributors will be engaged on terms acceptable to us. These distributors typically would sell a variety of other, non-competing products that may limit the resources they dedicate to selling the COV2T and/or SGT. In addition, we are unable to ensure that our distributors will comply with all applicable laws regarding the sale of our products. If our distributors fail to effectively market and sell the COV2T and/or SGT in full compliance with applicable laws, our operating results and business may suffer. Recruiting and retaining qualified third-party distributors and training them in our technology and product offering will require significant time and resources. To develop and expand our distribution, we will be required to scale and improve our processes and procedures that support our distributors. Further, if our relationship with a successful distributor terminates, we may be unable to replace that distributor without disruption to our business. If we fail to develop or maintain positive relationships with our distributors, including in new markets, fail to manage, train or incentivize these distributors effectively, or fail to provide distributors with competitive products on attractive terms, or if these distributors are not successful in their sales efforts, we may not achieve or may have a reduction in revenue and our operating results, reputation and business would be harmed.

Failure in our conventional, online and digital marketing efforts could impact our ability to generate sales.

We intend to engage in conventional marketing strategies and also may utilize online and digital marketing in order to create awareness to the COV2T and/or SGT. Our management believes that using a wide variety of marketing strategies, including online advertisement and a variety of other pay-for-performance methods may be effective for marketing and generating sales of the COV2T and/or SGT, as opposed to relying exclusively on traditional, expensive retail channels. In any event, there is a risk that any or all of our marketing strategies could fail. We cannot predict whether the use of traditional and/or non-traditional retail sales tools, in combination with reliance on healthcare providers to educate our customers about the COV2T and/or SGT, will be successful in effectively marketing the COV2T and/or SGT. The failure of our marketing efforts could negatively impact our ability to generate sales.

The COV2T and SGT may utilize a smart device platform and, in the future, other software platforms. If we are unable to achieve or maintain a good relationship with the providers of these platforms, or if a platform's application store (such as the App Store for iOS devices or the Google Play Store for Android devices), or any other applicable platform resource were unavailable for any prolonged period of time, our business will suffer.

A key component of the COV2T and SGT is a smart device application that includes tools to help patients manage their disease. This application will be compatible with various operating platforms. We will be subject to each of the standard terms and conditions for application developers, which govern the promotion, distribution and operation of applications through their respective app stores. If we are unable to make the COV2T or SGT application compatible with these platforms, or if we fail to comply with the standard terms and conditions for developers or there is any deterioration in our relationship with either platform providers or others after our application is available, our business would be materially harmed.

As we intend to conduct business internationally, we are susceptible to risks associated with international relationships.

We are based in the United States, and expect to market, promote and sell our products globally. The international nature of our business requires significant management attention, which could negatively affect our business if it diverts their attention from their other responsibilities. In addition, doing business with foreign customers subjects us to additional risks that companies do not generally face if they operate exclusively within a single jurisdiction. These risks and uncertainties include:

- different regulatory requirements for medical product approvals in foreign countries;
- different standards of care in various countries that could complicate the evaluation of our product candidates;
- different medical product import and export rules;
- different labor laws;
- reduced protection for intellectual property rights in certain countries;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- different reimbursement systems and different competitive medical products indicated for glucose testing;
- localization of products and services, including translation of foreign languages;
- delivery, logistics and storage costs;
- longer accounts receivable payment cycles and difficulties in collecting accounts receivable;
- difficulties providing customer services;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- compliance with the Foreign Corrupt Practices Act, or the “FCPA,” and other anti-corruption and anti-bribery laws;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- restrictions on the repatriation of earnings;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability resulting from development work conducted by third party foreign distributors; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters, management, communication and integration problems resulting from cultural differences and geographic dispersion.

The occurrence of any or all of these risks could adversely affect our business. In the event that we are unable to manage the complications associated with international operations, our results of operations, financial condition and business prospects could be materially and adversely affected.

If third-party payors do not provide coverage and reimbursement for the use of the COV2T and/or SGT, our business and prospects may be negatively impacted.

Third-party payors, whether governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, in certain countries, no uniform policy of coverage and reimbursement for medical device products and services exists among third-party payors. Therefore, coverage and reimbursement for medical device products and services can differ significantly from payor to payor. In addition, payors continually review new technologies for possible coverage and can, without notice, deny coverage for these new products and procedures. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained, or maintained if obtained. Reimbursement systems in international markets vary significantly by country and by region within some countries, and reimbursement approvals must be obtained on a country-by-country basis. In many international markets, a product must be approved for reimbursement before it can be approved for sale in that country. Further, many international markets have government-managed healthcare systems that control reimbursement for new devices and procedures. For example, no government in the areas where we hold our license has approved reimbursement of the SGT in particular. We believe that reimbursement will not be an issue as we intend to put this in the market at the same price as current reimbursed blood finger tests. In most markets, there are private insurance systems as well as government-managed systems. If sufficient coverage and reimbursement is not available for our current or future products, in any country where our license operates, the demand for our products and our revenues will be adversely affected.

Non-United States governments often impose strict price controls, which may adversely affect our future profitability.

We intend to seek approval to market the COV2T globally and the SGT across the APAC Region. If we obtain approval in one or more of the jurisdictions within our License Agreement, we will be subject to rules and regulations in those jurisdictions relating to our products. In some countries, pricing may be subject to governmental control under certain circumstances, which may vary country by country. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of requisite marketing approval. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical evaluation that compares the cost-effectiveness of our product to other available products. If reimbursement of our product candidates is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability. Price controls may reduce prices to levels significantly below those that would prevail in less regulated markets or limit the volume of products which may be sold, either of which may have a material and adverse effect on potential revenues from sales of the COV2T and/or SGT. Moreover, the process and timing for the implementation of price restrictions is unpredictable, which may cause potential revenues from the sales of the COV2T and/or SGT to fluctuate from period to period.

The COV2T and/or SGT, including its software and systems, may contain undetected errors, which could limit our ability to provide our products and services and diminish the attractiveness of our service offerings.

The COV2T and/or SGT may contain undetected errors, defects or bugs. As a result, our customers or end users may discover errors or defects in our products, software or systems, or our products, software or systems may not operate as expected. We may discover significant errors or defects in the future that we may not be able to fix. Our inability to fix any of those errors could limit our ability to provide our products and services, impair the reputation of our brand and diminish the attractiveness of our product and service offerings to our customers. In addition, we may utilize third party technology or components in our products, and we rely on those third parties to provide support services to us. The existence of errors, defects or bugs in third party technology or components, or the failure of those third parties to provide necessary support services to us, could materially adversely impact our business.

We will rely on the proper function, security and availability of our information technology systems and data to operate our business, and a breach, cyber-attack or other disruption to these systems or data could materially and adversely affect our business, results of operations, financial condition, cash flows, reputation or competitive position.

We will depend on sophisticated software and other information technology systems to operate our business, including to process, transmit and store sensitive data, and our products and services will include information technology systems that collect data regarding patients. We could experience attempted or actual interference with the integrity of, and interruptions in, our technology systems, as well as data breaches, such as cyber-attacks, malicious intrusions, breakdowns, interference with the integrity of our products and data or other significant disruptions. Furthermore, we may rely on third-party vendors to supply and/or support certain aspects of our information technology systems. These third-party systems could also become vulnerable to cyber-attack, malicious intrusions, breakdowns, interference or other significant disruptions, and may contain defects in design or manufacture or other problems that could result in system disruption or compromise the information security of our own systems. Our international operations mean that we are subject to laws and regulations, including data protection and cybersecurity laws and regulations, in many jurisdictions. Furthermore, there has been a developing trend of civil lawsuits and class actions relating to breaches of consumer data held by large companies or incidents arising from other cyber-attacks. Any data security breaches, cyber-attacks, malicious intrusions or significant disruptions could result in actions by regulatory bodies and/or civil litigation, any of which could materially and adversely affect our business, results of operations, financial condition, cash flows, reputation or competitive position. In addition, our information technology systems require an ongoing commitment of significant resources to maintain, protect, and enhance existing systems and develop new systems to keep pace with continuing changes in information processing technology, evolving legal and regulatory standards, the increasing need to protect patient and customer information, changes in the techniques used to obtain unauthorized access to data and information systems, and the information technology needs associated any new products and services. There can be no assurance that our process of consolidating, protecting, upgrading and expanding our systems and capabilities, continuing to build security into the design of our products, and developing new systems to keep pace with continuing changes in information processing technology will be successful or that additional systems issues will not arise in the future. If our information technology systems, products or services or sensitive data are compromised, patients or employees could be exposed to financial or medical identity theft or suffer a loss of product functionality, and we could lose existing customers, have difficulty attracting new customers, have difficulty preventing, detecting, and controlling fraud, be exposed to the loss or misuse of confidential information, have disputes with customers, physicians, and other health care professionals, suffer regulatory sanctions or penalties, experience increases in operating expenses or an impairment in our ability to conduct our operations, incur expenses or lose revenues as a result of a data privacy breach, product failure, information technology outages or disruptions, or suffer other adverse consequences including lawsuits or other legal action and damage to our reputation.

Our future performance will depend on the continued engagement of key members of our management team.

Our future performance depends to a large extent on the continued services of members of our current management including, in particular, our President & Chief Executive Officer and Chief Financial Officer. In the event that we lose the continued services of such key personnel for any reason, this could have a material adverse effect on our business, operations and prospects.

If we are not able to attract and retain highly skilled managerial, scientific and technical personnel, we may not be able to implement our business model successfully.

We believe that our management team must be able to act decisively to apply and adapt our business model in the markets in which we will compete. In addition, we will rely upon technical and scientific employees or third-party contractors to effectively establish, manage and grow our business. Consequently, we believe that our future viability will depend largely on our ability to attract and retain highly skilled managerial, sales, scientific and technical personnel. In order to do so, we may need to pay higher compensation or fees to our employees or consultants than we currently expect, and such higher compensation payments would have a negative effect on our operating results. Competition for experienced, high-quality personnel is intense and we cannot assure that we will be able to recruit and retain such personnel. We may not be able to hire or retain the necessary personnel to implement our business strategy. Our failure to hire and retain such personnel could impair our ability to develop new products and manage our business effectively.

If we or our manufacturers fail to comply with the regulatory quality system regulations or any applicable equivalent regulations, our proposed operations could be interrupted, and our operating results would suffer.

We and any third-party manufacturers and suppliers of ours will be required, to the extent of applicable regulation, to follow the quality system regulations of each jurisdiction we will seek to penetrate and also will be subject to the regulations of these jurisdictions regarding the manufacturing processes. If we or any third-party manufacturers or suppliers of ours are found to be in significant non-compliance or fail to take satisfactory corrective action in response to adverse regulatory findings in this regard, regulatory agencies could take enforcement actions against us and such manufacturers or suppliers, which could impair or prevent our ability to produce our products in a cost-effective and timely manner in order to meet customers' demands. Accordingly, our operating results would suffer.

We may be subject to healthcare fraud and abuse laws and regulations.

Many international healthcare laws and regulations apply to the glucose monitoring business and medical devices. We will be subject to certain regulations regarding commercial practices false claims. If our operations or arrangements are found to be in violation of governmental regulations, we may be subject to civil and criminal penalties, damages, fines and the curtailment of our operations. All of these penalties could adversely affect our ability to operate our business and our financial results.

Product liability suits, whether or not meritorious, could be brought against us due to an alleged defective product or for the misuse of the COV2T and/or SGT. These suits could result in expensive and time-consuming litigation, payment of substantial damages, and an increase in our insurance rates.

If the COV2T and/or SGT or any future diagnostic test based on the Biosensor Platform is defectively designed or manufactured, contains defective components or is misused, or if someone claims any of the foregoing, whether or not meritorious, we may become subject to substantial and costly litigation. Misusing our devices or failing to adhere to the operating guidelines or our devices producing inaccurate meter readings could cause significant harm to patients, including death. In addition, if our operating guidelines are found to be inadequate, we may be subject to liability. Product liability claims could divert management's attention from our core business, be expensive to defend and result in sizable damage awards against us. While we expect to maintain product liability insurance, we may not have sufficient insurance coverage for all future claims. Any product liability claims brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing continuing coverage, could harm our reputation in the industry and could reduce revenue. Product liability claims in excess of our insurance coverage would be paid out of cash reserves harming our financial condition and adversely affecting our results of operations.

If we are found to have violated laws protecting the confidentiality of patient health information, we could be subject to civil or criminal penalties, which could increase our liabilities and harm our reputation or our business.

Part of our business plan includes the storage and potential monetization of data of users of the COV2T and/or SGT. There are a number of laws around the world protecting the confidentiality of certain patient health information, including patient records, and restricting the use and disclosure of that protected information. Privacy rules protect medical records and other personal health information by limiting their use and disclosure, giving individuals the right to access, amend and seek accounting of their own health information and limiting most use and disclosures of health information to the minimum amount reasonably necessary to accomplish the intended purpose. We may face difficulties in holding such information in compliance with applicable law. If we are found to be in violation of the privacy rules, we could be subject to civil or criminal penalties, which could increase our liabilities, harm our reputation and have a material adverse effect on our business, financial condition and results of operations.

We are party to agreements pursuant to which we may be required to make payments to certain of our affiliates, which may reduce our cash flow and profits.

We are party to agreements (including the License Agreement) pursuant to which we may be required to make payments to certain of our affiliates as described in “*Certain Transactions*.” For instance, commencing after the receipt of SGT regulatory approval in any jurisdiction in the APAC Region, we may be required to pay the Minimum Royalty with respect to such jurisdiction to our largest stockholder, the Licensor, although the determination of the Minimum Royalty is subject to agreement between us and the Licensor as to certain parameters, as described elsewhere in this prospectus, with disputes generally resolved by an independent third party.

Risks Related to Product Development and Regulatory Approval

The regulatory approval process which we may be required to navigate may be expensive, time-consuming, and uncertain and may prevent us from obtaining clearance for the product launch of the SGT or our any future product.

It is anticipated that FDA review for COV2T will be under the Emergency Use Authorization program, which means expedited time to market. However, to date, we have not received regulatory approval in any jurisdiction. We intend to market the SGT following regulatory approval. To date, we have not received regulatory approval in any jurisdiction. However, we recently have engaged Emergo Global Consulting LLC, a clinical research and regulatory consulting firm specializing in high tech medical device development, and commenced the regulatory approval process in various jurisdictions in the APAC Region. The research, design, testing, manufacturing, labeling, selling, marketing and distribution of medical devices are subject to extensive regulation by country-specific regulatory authorities, which regulations differ from country to country. There can be no assurance that, even after such time and expenditures, we will be able to obtain necessary regulatory approvals for clinical testing or for the manufacturing or marketing of any products. In addition, during the regulatory process, other companies may develop other technologies with the same intended use as our products. We also will be subject to numerous post-marketing regulatory requirements, which may include labeling regulations and medical device reporting regulations, which may require us to report to different regulatory agencies if our device causes or contributes to a death or serious injury, or malfunctions in a way that would likely cause or contribute to a death or serious injury. In addition, these regulatory requirements may change in the future in a way that adversely affects us. If we fail to comply with present or future regulatory requirements that are applicable to us, we may be subject to enforcement action by regulatory agencies, which may include, among others, any of the following sanctions:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- customer notification, or orders for repair, replacement or refunds;
- voluntary or mandatory recall or seizure of our current or future products;
- imposing operating restrictions, suspension or shutdown of production;
- refusing our requests for clearance or pre-market approval of new products, new intended uses or modifications to the COV2T and/or SGT or future products;
- rescinding clearance or suspending or withdrawing pre-market approvals that have already been granted; and
- criminal prosecution.

The occurrence of any of these events may have a material adverse effect on our business, financial condition and results of operations.

Clinical data obtained subsequent to the implementation of the clinical evidence module may not meet the required objectives, which could delay, limit or prevent additional regulatory approval.

There can be no assurance that we will successfully complete any clinical evaluations necessary to receive regulatory approvals. While preliminary results have been encouraging and indicative of the potential performance of the SGT, data already obtained, or in the future obtained, from clinical studies do not necessarily predict the results that will be obtained from later clinical evaluations. The failure to adequately demonstrate the analytical performance characteristics of the device under development could delay or prevent regulatory approval of the device, which could prevent or result in delays to market launch and could materially harm our business. There can be no assurance that we will be able to receive approval for any potential applications of our principal technology, or that we will receive regulatory clearances from targeted regions or countries.

We may be unable to complete required clinical evaluations, or we may experience significant delays in completing such clinical evaluations, which could prevent or significantly delay our targeted product launch timeframe and impair our viability and business plan.

The completion of any future clinical evaluations for the COV2T and/or SGT, or other studies that we may be required to undertake in the future for the COV2T and/or SGT or other products based on the Biosensor Platform, could be delayed, suspended or terminated for several reasons, including:

- we may fail to or be unable to conduct the clinical evaluation in accordance with regulatory requirements;
- sites participating in the trial may drop out of the trial, which may require us to engage new sites for an expansion of the number of sites that are permitted to be involved in the trial;
- patients may not enroll in, remain in or complete, the clinical evaluation at the rates we expect; and
- clinical investigators may not perform our clinical evaluation on our anticipated schedule or consistent with the clinical evaluation protocol and good clinical practices.

If our clinical evaluations are delayed it will take us longer to ultimately launch the COV2T and/or SGT and our other products based on the Biosensor Platform in the market and generate revenues. Moreover, our development costs will increase if we have material delays in our clinical evaluation or if we need to perform more or larger clinical evaluations than planned.

We are subject to the risk of reliance on third parties to conduct our clinical evaluation work.

We will depend on independent clinical investigators to conduct our clinical evaluations. Contract research organizations may also assist us in the collection and analysis of data. These investigators and contract research organizations will not be our employees and we will not be able to control, other than by contract, the amount of resources, including time that they devote to products that we develop. If independent investigators fail to devote sufficient resources to our clinical evaluations, or if their performance is substandard, it will delay the approval or clearance and ultimately the market launch of any products that we develop. Further, regulatory bodies require that we comply with standards, commonly referred to as good clinical practice, for conducting, recording and reporting clinical evaluations to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial subjects are protected. If our independent clinical investigators and contract research organizations fail to comply with good clinical practice, the results of our clinical evaluations could be called into question and the clinical development of our product candidates could be delayed. Failure of clinical investigators or contract research organizations to meet their obligations to us or comply with applicable regulations could adversely affect the clinical development of our product candidates and harm our business. Moreover, we intend to have several clinical evaluations in order to support our marketing efforts and business development purposes. Such clinical evaluations will be conducted by third parties as well. Failure of such clinical evaluations to meet their primary endpoints could adversely affect our marketing efforts.

Risks Related to Our Intellectual Property

We depend on intellectual property licensed from the Licensor, and any absence of legal effect of the license or dispute over the license would significantly harm our business.

We are dependent on the intellectual property licensed from the Licensor. Although the License Agreement may not be terminated by the Licensor as long as we are continuing our operations, any absence of legal effect of the license could result in the loss of significant rights and could harm our ability to launch the COV2T and/or SGT in the market. Disputes may also arise between us and the Licensor regarding intellectual property subject to the License Agreement. If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, or are insufficient to provide us the necessary rights to use the intellectual property, we may be unable to successfully develop and launch the COV2T and/or SGT and our other product candidates. If we or the Licensor fail to adequately protect this intellectual property, our ability to launch our products in the market also could suffer. For so long as we are dependent on the intellectual property covered by the License Agreement for the pursuit of our business, any such disputes relating to the License Agreement or failure to protect the intellectual property could threaten our viability.

We will depend primarily on the Licensor to file, prosecute, maintain, defend and enforce intellectual property that we license from it and that is material to our business.

The intellectual property relating to the COV2T and/or SGT is owned by the Licensor. Under the License Agreement, the Licensor generally has the right to file, prosecute, maintain and defend the intellectual property we have licensed from the Licensor. If the Licensor fails to conduct these activities for intellectual property protection covering any of our product candidates, our ability to develop and launch those product candidates may be adversely affected and we may not be able to prevent competitors from making, using or selling competing products. In addition, pursuant to the terms of the License Agreement with the Licensor, the Licensor generally has the right to control the enforcement of our licensed intellectual property and the defense of any claims asserting the invalidity of that intellectual property. We cannot be certain that the Licensor will allocate sufficient resources to and otherwise prioritize the enforcement of such intellectual property or the defense of such claims to protect our interests in the licensed intellectual property. In the absence of action by the Licensor, we may be unable to protect and enforce the proprietary rights on which our business relies. Even if we are not a party to these legal actions, an adverse outcome could harm our business because it might prevent us from continuing to use the licensed intellectual property that we need to operate our business. In addition, even if we take control of the prosecution of licensed intellectual property and related applications, enforcement of licensed intellectual property, or defense of claims asserting the invalidity of that intellectual property, we may still be adversely affected or prejudiced by actions or inactions of the Licensor and its counsel that took place prior to or after our assuming control, and we cannot ensure the cooperation of the Licensor in any such action. Furthermore, if we take action to protect, enforce or defend the licensed intellectual property, we may incur significant costs and the attention of our management may be diverted from our normal business operations. As a result, our business, results of operations and financial condition could be materially and adversely affected.

We and the Licensor may be unable to protect or enforce the intellectual property rights licensed to us, which could impair our competitive position.

In order for our business to be viable and to compete effectively, the proprietary rights with respect to the technologies and intellectual property used in our products must be developed and maintained. The Licensor relies primarily on patent protection and trade secrets, as well as a combination of copyright and trademark laws and nondisclosure and confidentiality agreements to protect its technology and intellectual property rights. There are significant risks associated with the Licensor's ability (or our ability, in the absence of action by the Licensor) to protect the intellectual property licensed to us, including:

- pending intellectual property applications may not be approved or may take longer than expected to result in approval in one or more of the countries in which we operate;
- the Licensor's intellectual property rights may not provide meaningful protection;
- other companies may challenge the validity or extent of the Licensor's patents and other proprietary intellectual property rights through litigation, oppositions and other proceedings. These proceedings can be protracted as well as unpredictable;
- other companies may have independently developed (or may in the future independently develop) similar or alternative technologies, may duplicate the Licensor's technologies or may design their technologies around the Licensor's technologies;
- enforcement of intellectual property rights is complex, uncertain and expensive, and may be subject to lengthy delays. In the event we take control of any such action under the License Agreement, our ability to enforce our intellectual property protection could be limited by our financial resources; and
- the other risks described in "*—Risks Related to Our Intellectual Property.*"

If any of the Licensor's patents or other intellectual property rights fail to protect the technology licensed by us, it would make it easier for our competitors to offer similar products. Any inability on the Licensor's part (or on our part, in the absence of action by the Licensor) to adequately protect its intellectual property may have a material adverse effect on our business, financial condition and results of operations.

We and/or the Licensor may be subject to claims alleging the violation of the intellectual property rights of others.

We may face significant expense and liability as a result of litigation or other proceedings relating to intellectual property rights of others. In the event that another party has intellectual property protection relating to an invention or technology licensed by us from the Licensor, we and/or the Licensor may be required to participate in an interference proceeding declared by the regulatory authorities to determine priority of invention, which could result in substantial uncertainties and costs for us, even if the eventual outcome was favorable to us. We and/or the Licensor also could be required to participate in interference proceedings involving intellectual property of another entity. An adverse outcome in an interference proceeding could require us and/or the Licensor to cease using the technology, to substantially modify it or to license rights from prevailing third parties, which could delay or prevent the launch of our products in the market or adversely affect our profitability. The cost to us of any intellectual property litigation or other proceeding relating the intellectual property licensed by us from the Licensor, even if resolved in our favor, could be substantial, especially given our early stage of development. A third party may claim that we and/or the Licensor are using inventions claimed by their intellectual property and may go to court to stop us and/or the Licensor from engaging in our normal operations and activities, such as research, development and the sale of any future products. Such lawsuits are expensive and would consume significant time and other resources. There is a risk that a court will decide that we and/or the Licensor are infringing the third party's intellectual property and will order us to stop the activities claimed by the intellectual property. In addition, there is a risk that a court will order us and/or the Licensor to pay the other party damages for having infringed their intellectual property. While the Licensor is required to indemnify us for certain losses in connection with such proceedings, there can be no assurance that the Licensor will be able to satisfy any such obligation. Moreover, there is no guarantee that any prevailing intellectual property owner would offer us a license so that we could continue to engage in activities claimed by the intellectual property, or that such a license, if made available to us, could be acquired on commercially acceptable terms.

The Licensor has limited foreign intellectual property rights and may not be able to protect its intellectual property rights.

Our intellectual property rights consist primarily of intellectual property licensed from the Licensor. The Licensor has determined that filing, prosecuting and defending intellectual property on devices in all countries globally would be prohibitively expensive, and intellectual property rights in some countries can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property to the same extent as laws in the United States. Consequently, we and/or the Licensor may not be able to prevent third parties from practicing our inventions or from selling or importing products made using our inventions. Competitors may use our technologies in jurisdictions where we have not obtained intellectual property rights to develop their own products and further, may export otherwise infringing products to territories where we have intellectual property protection, but enforcement is not as strong as that in the United States. Policing unauthorized use of proprietary technology is difficult and expensive. The legal systems of certain countries do not favor the enforcement of trade secrets and other intellectual property, particularly those relating to medical device products, which could make it difficult for us to stop the infringement of our intellectual property or marketing of competing products in violation of our proprietary rights generally. An adverse determination or an insufficient damage award in any such litigation could materially impair our intellectual property rights and may otherwise harm our business. In addition, some developing countries in the APAC Region have compulsory licensing laws under which an intellectual property owner may be compelled to grant licenses to third parties. In those countries, we and/or the Licensor may have limited remedies if our intellectual property is infringed or if we and/or the Licensor are compelled to grant a license to a third party, which could materially diminish the value of that intellectual property. Furthermore, we may not be able to register or otherwise protect the trademark “Glucose Biosensor” in developing countries in the APAC Region.

We and the Licensor rely on confidentiality agreements that could be breached and may be difficult to enforce, which could result in third parties using our intellectual property to compete against us.

Although we believe that we and the Licensor take reasonable steps to protect our intellectual property, including the use of agreements relating to the non-disclosure of confidential information to third parties, as well as agreements that purport to require the disclosure and assignment to us of the rights to the ideas, developments, discoveries and inventions of our employees and consultants while we or the Licensor employ them, the agreements can be difficult and costly to enforce. Although we and the Licensor seek to enter into these types of agreements with contractors, consultants, advisors and research collaborators, to the extent that employees and consultants utilize or independently develop intellectual property in connection with any of our projects, disputes may arise as to the intellectual property rights associated with our technology. If a dispute arises, a court may determine that the right belongs to a third party. In addition, enforcement of our rights and the rights of the Licensor can be costly and unpredictable. We and the Licensor also rely on trade secrets and proprietary know-how that we and the Licensor may seek to protect in part by confidentiality agreements with employees, contractors, consultants, advisors or others. Despite the protective measures we employ, we and the Licensor still face the risk that:

- these agreements may be breached;
- these agreements may not provide adequate remedies for the applicable type of breach;
- our proprietary know-how will otherwise become known; or
- our competitors will independently develop similar technology or proprietary information.

We and the Licensor may be subject to claims challenging the invention of the intellectual property that we license from the Licensor.

We and the Licensor may be subject to claims that former employees, collaborators or other third parties have an interest in intellectual property as an inventor or co-inventor. For example, we and the Licensor may have inventorship disputes arising from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship. If we and the Licensor fail in defending any such claims, in addition to paying monetary damages, we and the Licensor may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. As a result, it is unclear whether and, if so, to what extent employees of ours and the Licensor may be able to claim compensation with respect to our future revenue. We may receive less revenue from future products if any of employees of the Licensor or us successfully claim compensation for their work in developing our intellectual property, which in turn could impact our future profitability.

Risks Related to Our Industry

We face intense competition in the self-monitoring of glucose market, particularly blood-based products, and as a result we may be unable to effectively compete in our industry.

With our second product from the platform, the SGT, we expect to compete directly and primarily with large medical device companies, as well as with second and third tier companies having various levels of sophistication and resources. The large companies have most of the glucose monitoring business and strong research and development capacity. Their dominant market position over the last few decades and significant control over markets could significantly limit our ability to introduce the SGT or effectively market and generate sales of the product. We have not yet entered the revenue stage and most of our competitors have long histories and strong reputations within the industry. They have significantly greater brand recognition, financial and human resources than we do. They also have more experience and capabilities in researching and developing testing devices, obtaining and maintaining regulatory clearances and other requirements, manufacturing and marketing those products than we do. There is a significant risk that we may be unable to overcome the advantages held by our competition, and our inability to do so could lead to the failure of our business. Competition in the glucose monitoring markets is intense, which can lead to, among other things, price reductions, longer selling cycles, lower product margins, loss of market share and additional working capital requirements. To succeed, we must, among other critical matters, gain consumer acceptance for the SGT, technical solutions, prices and response time, or a combination of these factors, other than those of other competitors. If our competitors offer significant discounts on certain products, we may need to lower our prices or offer other favorable terms in order to compete successfully. Moreover, any broad-based changes to our prices and pricing policies could make it difficult to generate revenues or cause our revenues, if established, to decline. Moreover, if our competitors develop and commercialize products that are more desirable than the SGT or the other products that we may develop, we may not convince customers to use our products. Any such changes would likely reduce our commercial opportunity and revenue potential and could materially adversely impact our operating results.

If we or the Licensor fail to respond quickly to technological developments, our products may become uncompetitive and obsolete.

The glucose monitoring market may experience rapid technology developments, changes in industry standards, changes in customer requirements and frequent new product introductions and improvements. If we or the Licensor are unable to respond to these developments, we may lose competitive position, and the SGT or any other device or technology may become uncompetitive or obsolete, causing our business and prospects to suffer. In order to compete, we and the Licensor may have to develop, license or acquire new technology on a schedule that keeps pace with technological developments and the requirements for products addressing a broad spectrum and designers and designer expertise in our industries.

We are susceptible to economic conditions and conducting operations in the Asia Pacific Region

General economic conditions in APAC and China have an impact on our business and financial results. Weak economic conditions or softness in the consumer or business demand in APAC and China could result in lower demand for our services, which would likely have an adverse impact on our earnings and cash flows. Economic rebalancing policies recently adopted by the Chinese government have had a positive effect on the economic development of the country, but the government can change these economic reforms or any of the legal systems at any time. This could either benefit or damage our operations and profitability.

The medical device and other medical product industries in the APAC Region generally are highly regulated and such regulations are subject to change.

The medical device and other medical product industries in the APAC Region generally are subject to comprehensive government regulation and supervision, encompassing the approval, registration, manufacturing, packaging, licensing and marketing of new products. In addition, the regulatory frameworks in the APAC Region regarding our industry are subject to change. Any such changes may result in increased compliance costs on our business or cause delays in or prevent the successful development or launch of our product candidates in the APAC Region. The regulatory authorities in the countries and territories constituting the APAC Region also may launch investigations of individual companies or on an industry-wide basis. The costs and time necessary to respond to an investigation can be material. Any failure by us or our partners to maintain compliance with applicable laws and regulations or obtain and maintain required licenses and permits may result in the suspension or termination of our business activities in certain countries and territories in the APAC Region or in the region as a whole.

Fluctuation in the value of foreign currencies may have a material adverse effect on your investment.

A substantial portion of our revenues and costs may be denominated in foreign currencies, such as the Australian Dollar or Japanese Yen. Any significant change in value of these foreign currencies against the U.S. dollar may materially affect our cash flows, net revenues, earnings and financial position, and the value of, and any dividends payable on, our common stock in U.S. dollars. For example, an appreciation of any such foreign currency against the U.S. dollar would make any new investments or expenditures denominated in the foreign currency costlier to us, to the extent that we need to convert U.S. dollars into the foreign currency for such purposes. Conversely, a significant depreciation of any such foreign currency against the U.S. dollar may significantly reduce the U.S. dollar equivalent of our earnings, which in turn could adversely affect the price of our common stock. If we decide to convert any such foreign currency into U.S. dollars for the purpose of making payments for dividends on our common stock, strategic acquisitions or investments or other business purposes, appreciation of the U.S. dollar against the foreign currency would have a negative effect on the U.S. dollar amount available to us. We do not expect to hedge against the risks associated with fluctuations in exchange rates and, therefore, exchange rate fluctuations could have an adverse impact on our future operating results. As a result, fluctuations in exchange rates may have a material adverse effect on your investment.

We may be subject to tax inefficiencies and have not ascertained the impact on us of the new United States tax laws.

The tax regulations of the United States and other jurisdictions in which we operate are extremely complex and subject to change. New laws, new interpretations of existing laws, such as the Base Erosion Profit Shifting project initiated by the Organization for Economic Co-operation and Development and any legislation proposed by the relevant taxing authorities, or limitations on our ability to structure our operations and intercompany transactions may lead to inefficient tax treatment of our revenue, profits, royalties and distributions, if any are achieved. In the United States, in December 2017, comprehensive tax reform was enacted. We have not yet ascertained what impact the new law will have on our future effective tax rate, corporate structure and us in general. In addition, we and our foreign subsidiaries will have various intercompany transactions. We may not be able to obtain certain benefits under relevant tax treaties to avoid double taxation on certain transactions among our subsidiaries. If we are not able to avail ourselves of the tax treaties, we could be subject to additional taxes, which could adversely affect our financial condition and results of operations.

We are subject to laws and regulations governing business conduct, which will require us to develop and implement costly compliance programs.

We must comply with a wide range of laws and regulations to prevent corruption, bribery, and other unethical business practices, including the FCPA, anti-bribery and anti-corruption laws in other countries. The creation and implementation of international business practices compliance programs is costly and such programs are difficult to enforce, particularly where reliance on third parties is required. Anti-bribery laws prohibit us, our employees, and some of our agents or representatives from offering or providing any personal benefit to covered government officials to influence their performance of their duties or induce them to serve interests other than the missions of the public organizations in which they serve. Certain commercial bribery rules also prohibit offering or providing any personal benefit to employees and representatives of commercial companies to influence their performance of their duties or induce them to serve interests other than their employers. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring us to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and devise and maintain an adequate system of internal accounting controls for international operations. The anti-bribery provisions of the FCPA are enforced primarily by the Department of Justice. The SEC is involved with enforcement of the books and records provisions of the FCPA. Compliance with these anti-bribery laws is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the anti-bribery laws present particular challenges in the medical products industries because in many countries, a majority of hospitals are state-owned or operated by the government, and doctors and other hospital employees are considered civil servants. Furthermore, in certain countries, hospitals and clinics are permitted to sell medical devices to their patients and are primary or significant distributors of medical devices. Certain payments to hospitals in connection with clinical studies, procurement of medical devices and other work have been deemed to be improper payments to government officials that have led to vigorous anti-bribery law enforcement actions and heavy fines in multiple jurisdictions, particularly in the United States and China. It is not always possible to identify and deter violations, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. In the medical products industries, corrupt practices include, among others, acceptance of kickbacks, bribes or other illegal gains or benefits by the hospitals and medical practitioners from medical device manufacturers, distributors or their third-party agents in connection with the prescription of certain medical devices or disposables. If our employees, affiliates, distributors or third-party marketing firms violate these laws or otherwise engage in illegal practices with respect to their sales or marketing of our products or other activities involving our products, we could be required to pay damages or heavy fines by multiple jurisdictions where we operate, which could materially and adversely affect our financial condition and results of operations. Our potential customers also may deny access to sales representatives from medical device companies because the potential customers want to avoid the perception of corruption, which could adversely affect our ability to promote our products. As we expand our operations in the APAC Region, we will need to increase the scope of our compliance programs to address the risks relating to the potential for violations of the FCPA and other anti-bribery and anti-corruption laws. Our compliance programs will need to include policies addressing not only the FCPA, but also the provisions of a variety of anti-bribery and anti-corruption laws in multiple jurisdictions, including provisions relating to books and records that apply to us as a public company, and will need to include effective training for our personnel throughout our organization. The creation and implementation of anti-corruption compliance programs is costly and such programs are difficult to enforce, particularly where reliance on third parties is required. Violation of the FCPA and other anti-corruption laws can result in significant administrative and criminal penalties for us and our employees, including substantial fines, suspension or debarment from government contracting, prison sentences, or even the death penalty in extremely serious cases in certain countries. The SEC also may suspend or bar us from trading securities on United States exchanges for violation of the FCPA's accounting provisions. Even if we are not ultimately punished by government authorities, the costs of investigation and review, distraction of company personnel, legal defense costs, and harm to our reputation could be substantial and could limit our profitability or our ability to develop or launch our product candidates. In addition, if any of our competitors are not subject to the FCPA, they may engage in practices that will lead to their receipt of preferential treatment from potential customers and enable them to secure business from potential customers in ways that are unavailable to us.

Changes in the economic, political or social conditions or government policies in the APAC Region could have a material adverse effect on our business and operations.

The economies and societies of certain countries and territories in the APAC Region, continue to undergo significant change. Adverse changes in the political and economic policies in these countries and territories could have a material adverse effect on the overall economic growth of these countries and territories, which could adversely affect our ability to conduct business in these countries and territories. The governments of these countries and territories continue to adjust economic policies to promote economic growth. Some of these measures may benefit the overall economy, but may also have a negative effect on us. As the medical product industry grows and evolves in these countries and territories, the governments may also implement measures to change the structure of foreign investment in this industry. We are unable to predict any such policy changes, any of which could materially and adversely affect our ability to finance or conduct our business in these countries and territories. Any failure on our part to comply with changing government regulations and policies could result in the loss of our ability to develop and launch our product candidates in these countries and territories.

Our customers for the Saliva Glucose Test initially may be concentrated in China; in which case we may be susceptible to risks specifically associated with business activities in China.

On May 1, 2020, our parent company, LSB D (Life Science Biosensor Diagnostics Pty Ltd), filed a submission with the FDA for the Saliva Glucose Biosensor Diagnostic Test, currently in development as a point-of-care test intended to replace blood glucose testing for diabetes management. Following the 513(g) submission to the FDA (Submitted May 01, 2020), it was determined that the company could seek the De Novo application pathway for the Saliva Glucose Biosensor Diagnostic Test, we were appointed an expert contact person, Acting Branch Chief from the Diabetes Diagnostic Devices Branch. We have further commenced planning discussions with the FDA Office of In Vitro Diagnostics and Radiological Health and the Office of Product Evaluation and Quality pertaining to the clinical development and study plan of the Saliva Glucose Biosensor. LSB D have completed the supplier evaluation process and identified a suitable partner to implement the clinical plan once approved by the FDA. We expect to leverage synergies from the approval process with the FDA within the Asia Pacific region, where China has the highest number of people with diabetes. We will first seek regulatory approval for the SGT with the NMPA of China and also other regulatory agencies that serve as reference regulators, such as the FDA, the European CE approval bodies and the Japanese regulatory bodies. To the extent we have operations in China and our customers initially are concentrated in China, we may be subject to additional risks specific to China that companies do not generally face if they operate primarily outside of China. These risks and uncertainties include:

- the Ministry of Commerce in China or its local counterpart must approve the amount and use of any capital contributions from us to our Chinese subsidiary, which may inhibit our ability to contribute additional capital to fund our Chinese operations;
- the Chinese government imposes controls on the convertibility of the Renminbi into foreign currencies and the remittance of foreign currency out of China for certain transactions, which may restrict the ability of our operating subsidiary in China to remit sufficient foreign currency to pay dividends or other payments to us;
- the legal system of China is a civil law system that continues to rapidly evolve, and the laws, regulations and rules are not always uniformly interpreted or enforced, which may limit legal protections available to us;
- our operations in China subject us to various Chinese labor and social insurance laws, and any failure to comply with such laws could subject us to late fees, fines and penalties, or cause the suspension or termination of our ability to conduct business in China; and
- failure to make adequate contributions to various employee benefit plans as required by Chinese regulations may subject us to penalties.

In the event that we are unable to manage the complications associated with operations in China, our results of operations, financial condition and business prospects could be materially and adversely affected.

Risks Related to the Ownership of Our Common Stock

We may not be able to satisfy the continued listing requirements of the NASDAQ Global Market in order to maintain the listing of our common stock.

We must meet certain financial and liquidity criteria to maintain the listing of our common stock on the NASDAQ Global Market. If we fail to meet any of continued listing standards, our common stock may be delisted. In addition, while we have no present intention to do so, our Board of Directors may determine that the cost of maintaining our listing on a national securities exchange outweighs the benefits of such listing. A delisting of our common stock from the NASDAQ Global Market may have materially adverse consequences to our stockholders, including:

- a reduced market price and liquidity with respect to our shares of common stock;
- limited dissemination of the market price of our common stock;
- limited news coverage;
- limited interest by investors in our common stock;
- volatility of the prices of our common stock, due to low trading volume;
- our common stock being considered a “penny stock,” which would result in broker-dealers participating in sales of our common stock being subject to the regulations set forth in Rules 15c-2 through 15c-9 promulgated under the Exchange Act;
- increased difficulty in selling our common stock in certain states due to “blue sky” restrictions; and
- limited ability to issue additional securities or to secure additional financing.

If our common stock is delisted, we may seek to have our common stock quoted on an over-the-counter marketplace, such as on the OTCQX. The OTCQX is not a stock exchange, and if our common stock trades on the OTCQX rather than a securities exchange, there may be significantly less trading volume and analyst coverage of, and significantly less investor interest in, our common stock, which may lead to lower trading prices for our common stock.

The market price of our common stock may be significantly volatile.

The market price for our common stock may be significantly volatile and subject to wide fluctuations in response to factors including the following:

- developments prior to commercial sales relating to regulatory approval, manufacturing and distribution of our products;
- actual or anticipated fluctuations in our quarterly or annual operating results;
- changes in financial or operational estimates or projections;
- conditions in markets generally;

- changes in the economic performance or market valuations of companies similar to ours; and
- general economic or political conditions in the United States or elsewhere.

In particular, the market prices for securities of medical device companies have historically been particularly volatile. Some of the factors that may cause the market price of our common stock to fluctuate include:

- any delay in or the results of our clinical evaluations;
- any delay in manufacturing of our products;
- any delay with the approval for reimbursement for the patients from their insurance companies;
- our failure to comply with regulatory requirements;
- the announcements of clinical evaluation data, and the investment community's perception of and reaction to those data;
- the results of clinical evaluations conducted by others on products that would compete with ours;
- any delay or failure to receive clearance or approval from regulatory agencies or bodies;
- our inability to commercially launch products or market and generate sales of our products, including the SGT;
- failure of the SGT or any other products, even if approved for marketing, to achieve any level of commercial success;
- our failure to obtain intellectual property protection for any of our technologies and products (including those related to the SGT) or the issuance of third-party intellectual property that cover our proposed technologies or products;
- developments or disputes concerning our product's intellectual property rights;
- our or our competitors' technological innovations;
- general and industry-specific economic conditions that may affect our expenditures;
- changes in market valuations of similar companies;
- announcements by us or our competitors of significant contracts, acquisitions, strategic partnerships, joint ventures, capital commitments, new technologies, or intellectual property;
- failure to adequately manufacture the SGT or any other products through third parties;
- future sales of our common stock or other securities, including shares issuable upon the exercise of outstanding warrants or otherwise issued pursuant to certain contractual rights;
- period-to-period fluctuations in our financial results; and
- low or high trading volume of our common stock due to many factors, including the terms of our financing arrangements.

In addition, if we fail to reach an important research, development or commercialization milestone or result by a publicly expected deadline, even if by only a small margin, there could be significant impact on the market price of our common stock. Additionally, as we approach the announcement of anticipated significant information and as we announce such information, we expect the price of our common stock to be volatile and negative results would have a substantial negative impact on the price of our common stock. In some cases, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm our business operations and reputation.

There is no public market for the Series B Convertible Preferred Stock and an active trading market for the same is not expected to develop.

There is no established public trading market for the Series B Convertible Preferred Stock and we do not expect a market to develop. Without an active market, the liquidity of such securities will be severely limited.

Holders of our preferred stock will have no rights as common stockholders with respect to the shares of common stock underlying the Preferred Stock until they acquire our common stock.

Until preferred holders acquire our common stock upon conversion of their preferred stock, they will have no rights with respect to the common stock underlying such securities. Upon conversion, they will be entitled to exercise the rights of a common stockholder only as to matters for which the record date for actions to be taken by our common stockholders occurs after the date such conversion.

LBSD, our largest stockholder may, exert significant influence over our affairs, including the outcome of matters requiring stockholder approval.

LBSD, our largest stockholder, controls 42.6% (as of June 30, 2021) of the total voting power of our outstanding common stock. Accordingly, the Licensor has the ability to control the election of our directors and the outcome of corporate actions requiring stockholder approval, such as: (i) a merger or a sale of our company, (ii) a sale of all or substantially all of our assets, and (iii) amendments to our certificate of incorporation and by-laws. This concentration of voting power and control could have a significant effect in delaying, deferring or preventing an action that might otherwise be beneficial to our other stockholders and be disadvantageous to our stockholders with interests different from the Licensor.

We are obligated to develop and maintain a system of effective internal control over financial reporting. We may not complete our analysis of our internal control over financial reporting in a timely manner, or these internal controls may not be determined to be effective, which may harm investor confidence in our company and, as a result, the value of our common stock.

We will be required, pursuant to Section 404 of the Sarbanes-Oxley Act, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting in the second annual report we file with the SEC. This assessment will need to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. However, our auditors will not be required to formally attest to the effectiveness of our internal control over financial reporting pursuant to Section 404 until we are no longer an "emerging growth company" as defined in the JOBS Act, if we take advantage of the exemptions available to us through the JOBS Act. Even after we cease to be an "emerging growth company," our auditors will not be required to formally attest to the effectiveness of our internal control over financial reporting unless we are an accelerated filer or a large accelerated filer (as defined under the Exchange Act). We are in the very early stages of the costly and challenging process of compiling the system and process documentation necessary to perform the evaluation needed to comply with Section 404. In this regard, we will need to continue to dedicate internal resources, engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. As we transition to the requirements of reporting as a public company, we may need to add additional finance staff. We may not be able to complete our evaluation and testing in a timely fashion. During the evaluation and testing process, if we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal controls are effective. We may not be able to remediate any material weaknesses in a timely fashion. If we are unable to complete our evaluation and testing, or if we are unable to assert that our internal control over financial reporting is effective, particularly if we have been unable to remediate any material weaknesses identified, or if our auditors, when required to do so, are unable to express an opinion that our internal controls are effective, investors could lose confidence in the accuracy and completeness of our financial reports, which could harm our stock price.

We are an emerging growth company and currently have limited accounting personnel and other supervisory resources. This can result in lack of necessary resources to adequately execute its accounting processes and address its internal controls over financial reporting requirements.

The Company is an emerging growth company which completed the IPO in December 2020. Prior to the IPO, the Company was a private corporation with limited accounting personnel and other supervisory resources necessary to adequately execute its accounting processes and address its internal controls over financial reporting requirements. As a result, previously existing internal controls are no longer sufficient, and the Company is in the process of updating these controls. The design and implementation of internal control over financial reporting for the Company's post-IPO has required and will continue to require significant time and resources from management and other personnel.

As part of this updating process, our management identified a material weakness in its internal control over financial reporting. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. The material weakness identified relates to the fact that the Company has not yet designed and maintained an effective control environment commensurate with its financial reporting requirements, including a) has not yet completed the formally documented policies and procedures with respect to the review, supervision and monitoring of the Company's accounting and reporting functions and b) lack of evidence to support the performance of controls and the adequacy of review procedures, including the completeness and accuracy of information used in the performance of controls.

We will incur increased costs as a result of operating as a public company and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices. Moreover, our ability to comply with all applicable laws, rules and regulations is uncertain given our management's relative inexperience with operating United States public companies.

As a public company, and particularly after we are no longer an "emerging growth company," we will incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, the listing requirements of the NASDAQ Global Market and other applicable securities rules and regulations impose various requirements on public companies. Our management and other personnel will need to devote a substantial amount of time to compliance with these requirements. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain directors' and officers' liability insurance, which could make it more difficult for us to attract and retain qualified members of our board of directors. Furthermore, new or changing laws, regulations and standards are subject to varying interpretations in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies, which could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We cannot predict or estimate the amount of additional costs we will incur as a public company or the timing of such costs. Moreover, our executive officers have little experience in operating a United States public company, which makes our ability to comply with applicable laws, rules and regulations uncertain. Our failure to comply with all laws, rules and regulations applicable to United States public companies could subject us or our management to regulatory scrutiny or sanction, which could harm our reputation and stock price.

ITEM 1B. UNRESOLVED STAFF COMMENTS.

None.

ITEM 2. PROPERTIES.

Effective September 1, 2021, we moved our principal executive office from 708 Third Avenue, 6th floor, New York, NY, 10017 to 420 Lexington Ave, New York, NY, 10170, where we lease approximately 320 square feet of office space pursuant to a monthly lease.

We believe that we have adequate space for our anticipated needs and that suitable additional space will be available at commercially reasonable prices as needed.

ITEM 3. LEGAL PROCEEDINGS.

From time to time, we may be subject to legal proceedings and claims arising in the ordinary course of business. We are not currently engaged in any material legal proceedings.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED SHAREHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

Market Information

Our common stock is traded on The Nasdaq Global Market under the symbol "GBS".

Holders

As of September 13, 2021, there are approximately 399 holders of record of our common stock. As many of our shares of common stock are held by brokers or other institutions on behalf of shareholders, we are unable to estimate the total number of individual shareholders represented by the record holders.

Dividends

We have not paid any dividends on our common stock to date and we currently expect that, for the foreseeable future, all earnings (if any) will be retained for the development of our business and no dividends will be declared or paid. In the future, our Board of Directors may decide, at their discretion, whether dividends may be declared and paid, taking into consideration, among other things, our earnings (if any), operating results, financial condition and capital requirements, general business conditions and other pertinent facts, including restrictions imposed by foreign jurisdictions on paying dividends or making other payments to us.

Stock Performance Graph

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information otherwise required under this item.

Recent Sales of Unregistered Securities

None.

Purchase of Our Equity Securities

None.

Securities Authorized for Issuance Under Equity Compensation Plans

See Item 12. "Security Ownership of Certain Beneficial Owners and Management Related Stockholders Matters" for information with respect to our compensation plans under which equity securities are authorized for issuance.

ITEM 6. RESERVED

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

In addition to historical information, this discussion contains forward-looking statements based upon management's current expectations that are subject to risks and uncertainties which may cause our actual results to differ materially from plans and results discussed herein. We encourage you to review the risks and uncertainties discussed in the sections entitled Item 1A. "Risk Factors" and "Cautionary Note Regarding Forward-Looking Statements" included at the beginning of this Annual Report on Form 10-K.

We caution readers not to place undue reliance on any forward-looking statements made by us, which speak only as of the date they are made. In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this report, and while we believe such information forms a reasonable basis for such. We disclaim any obligation, except as specifically required by law and the rules of the SEC, to publicly update or revise any such statements to reflect any change in our expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.

Overview

We are a biosensor diagnostic technology company developing our COV2 test and across the Asia-Pacific region (“APAC”) and a biosensor platform comprising of biochemistry, immunology, tumour markers, hormones, and nucleic acid diagnostic modalities. We were incorporated under the laws of Delaware on December 5, 2016. Our headquarter is in New York. We were formed to provide a non-invasive, pain free innovation to make it easier for people to manage diabetes using the Company’s Saliva Glucose Biosensor (“SGB” and, together with the software app that interfaces the SGB with the Company’s digital information system, the “SGT”)

We currently are a 42.6% (as of June 30, 2021) owned (by voting rights) affiliate of Life Science Biosensor Diagnostics Pty Ltd (“LSBD” or Licensor), an Australian company that owns the worldwide intellectual property rights to the biosensor platform from University of Newcastle, Australia. LSBD has licensed to us that technology for us to introduce and launch the platform in the APAC Region. We will commence this process with the SGT.

Our objective is to introduce and launch a COV2 test globally and then the SGB, the second of our diagnostic tests that stem from the Biosensor Platform that we license, in the APAC Region. In the next four years we intend on developing the platform to its full capacity testing across the following diagnostic modalities: immunology, hormones, chemistry, tumor markers and nucleic acid tests.

We believe that the COVID-19 pandemic is likely to remain with us for many years. Development of an improved antibody assays to detect prior infection with SARS-CoV-2 has been identified as one of the top unmet needs in the ongoing COVID-19 pandemic response. Precise knowledge of SARS-CoV-2 infection at the individual level can potentially inform clinical decision-making, whereas at the population level, precise knowledge of prior infection, immunity, and attack rates (particularly asymptomatic infection) is needed to prioritize risk management decision-making about social distancing, treatments, and vaccination. If saliva can support measurements of both the presence of SARS-CoV-2 RNA26-28 as well as antibodies against SARS-CoV-2, this sample type could provide an important opportunity to monitor individual and population-level SARS-CoV-2 transmission, infection, and immunity dynamics over place and time.

We anticipate there to be 3 different applications for the foreseeable future:

1. Population Screening - SARS-CoV-2 antibody testing is urgently needed to estimate the incidence and prevalence of SARS-CoV-2 infection at the general population level. Precise knowledge of population immunity could allow government bodies to make informed decisions about how and when to relax stay-at-home directives and to reopen the economy.
2. Diagnosis – The COV2 Biosensor test can be used as a complement to the (RNA) virus detection tests for patients presenting late after symptoms onset to healthcare facilities and where virus detection tests are negative despite strong indications of infection. In addition, they can potentially be used for informing the decision on discharge of patients who recovered from SARS-CoV-2 infection but remain RNA-positive by RT-PCR for a long time after symptoms have subsided. The degree of protective immunity conferred by or correlated with the antibodies detected in subjects with past SARS-CoV-2 infection is still under investigation. Once this is clarified, the COV 2 antibody tests could be, together with the (RNA) direct virus detection, an essential tool in de-escalation strategies. Currently antibody tests are used for sero-epidemiological surveys and studies.
3. Post vaccination screening - To assess the degree of the elicited potent antigen-specific antibody responses, to COV2 vaccines when developed and administered to humans.

Based on a recent paper publicly available and authored by the team at Johns Hopkins Department of Environmental Health and Engineering, Bloomberg School of Public Health, results indicate it is feasible to accurately measure the salivary IgG response to identify individuals with a prior SARS-CoV-2 infection. A saliva-based approach could serve as a non-invasive approach for accurate and large-scale SARS-CoV-2 “sero”-surveillance.

A saliva antibody test can greatly increase the scale of testing—particularly among susceptible populations—compared to blood and could clarify population immunity and susceptibility to SARS-CoV-2. The team at John Hopkins further demonstrated in the laboratory that when saliva was collected ≥ 10 days post symptom onset, the anti-SARS-CoV-2 IgG assay detects SARS-CoV-2 infection with 100% sensitivity and 99% specificity. In addition, the team demonstrated that the temporal kinetics of SARS CoV-2-specific IgG responses in saliva are consistent with those observed in serum and indicate that most individuals seroconvert approximately 10 days after COVID-19 symptom onset or approximately two weeks post-presumed infection.

By utilizing the biosensor platform for detecting COV2 we expect to have lower detection limits, improve on sensitivity and specificity characteristics of current diagnostic methods, be able to provide real time results at the point of care and provide quantitative results as opposed to negative or positive which is how other POCT report the results.

Accurate and scalable point-of-care (POC) tests for the diagnosis of COVID-19 would increase the scope for diagnosis to be made in the community and outside the laboratory setting They would have the potential to reduce the time to obtaining an actionable result, could support early identification of those with COVID-19 and could also support appropriate use of isolation resources, infection control measures, and recruitment into clinical trials of treatments.

We are progressing with the milestone of integrating Harvard University’s technology with our biosensor applications for SARS-Cov-2 antibody test for COVID-19 by entering on January 5, 2021, into a Research Collaboration Agreement with Harvard College for the purposes of facilitating mutual collaboration in scientific research in connection with the Company’s non-exclusive royalty free license to combat COVID-19 coronavirus. The contemplated collaboration includes research teams from the Company and Harvard and will include, among others, exchange of materials and research data.

Our Company has not generated any revenues to date. As such, the Company is subject to all of the risks associated with emerging growth companies. Since inception, the Company has incurred losses and negative cash flows from operating activities. The Company does not expect to generate positive cash flows from operating activities in the near future until such time, if at all, the Company completes the development process of its products, including regulatory approvals, and thereafter, begins to commercialize and achieve substantial acceptance in the marketplace for the first of a series of products in its medical device portfolio.

Recent Developments

On December 14, 2020, the Company agreed to issue to LSB, in consideration of LSB’s contribution towards the research and development of applications other than glucose and COVID-19 applications to a maximum of \$2 million over a 5-year period, a 5-year non-transferable warrant to purchase 3,000,000 shares of the Company’s common stock at the exercise price of \$17.00 per share.

On December 18, 2020, the Company entered into an Exchange Agreement (the “EA”) with LSB to exchange 3,000,000 shares of its common stock held by LSB for 3,000,000 shares of the Company’s Series B Convertible Preferred Stock. In addition, the parties to the Exchange Agreement entered into a Registration Rights Agreement (the “RRA”) pursuant to which the Company agreed to prepare and file within 30 days following the closing of the IPO with the Securities and Exchange Commission a registration statement to register for resale the shares of Common Stock issuable upon conversion of the Series B Convertible Preferred Stock. If and to the extent the Company fails to, among other things, file such resale registration statement or have it declared as required under the terms of the RRA, the Company will be required to pay to the holder of such registration rights partial liquidated damages payable in cash in the amount equal to the product of 1.0% multiplied by the aggregate purchase price paid by such holder pursuant to the EA. The EA and the RRA contain customary representations, warranties, agreements and, indemnification rights and obligations of the parties.

On December 18, 2020, LSBDD entered into a certain Purchase and Assignment Agreement (the “PAA”) with an institutional accredited investor (the “Purchaser”) pursuant to which LSBDD sold and assigned to the Purchaser 3,000,000 shares of the Series B Convertible Preferred Stock and assigned to the Purchaser its rights under the EA and the RRA with respect to such preferred shares for a total purchase price of \$2,000,000. The investor’s Series B Convertible Preferred Stock is convertible into 3,000,000 shares of the Company’s common stock, subject to beneficial ownership limitation.

On March 31, 2021, GBS entered into an agreement with LSBDD to provide GBS an option to acquire an exclusive license to use LSBDD’s intellectual property in the treatment or management of diabetes field in North America (the “Option Agreement”). The Option Agreement has a term of two years and the exercise price for the option is \$5 million.

Since completion of the initial public offering in December 2020, Series A and Series B warrants held by certain shareholders were exercised. Each warrant is convertible into 1 share of the Company’s common stock. A total of 59,800 Series A warrants and 1,400,995 Series B warrants were exercised and converted into common stock. In addition to this, a total of 1,700,000 Series B Convertible Preferred Stock was converted into common stock. Each share of Series B Convertible Preferred Stock is convertible into 1 share of the Company’s common stock as described in the Company’s Registration Statement on Form S-1, File No. 333-242277 with the U.S. Securities and Exchange Commission.

Point-of-Care Test Commercialization Ecosystem Established

- Received approval from the Harvard Longwood campus Institutional Review Board (IRB) to commence a study to test clinical samples from a COVID-19 repository and to commence clinical studies on the COVID-19 Antibody Biosensor;
- Onboarded and aligned with world-class institutions, Johns Hopkins University, The Wyss Institute for Biologically Inspired Engineering, and the University of Newcastle for the development of saliva-based POCTs for both glucose monitoring and COVID-19 antibody detection;
- Onboarded new top-tier members to GBS’s scientific team to formulate and execute its commercialization plan.

COVID-19 Key Developments

- Commenced research protocols with The Wyss Institute for Biologically Inspired Engineering to progress with the milestone of integrating this technology with the Company’s Biosensor for SARS-Cov-2 antibody tests;
- Initiated study for the salivary collection protocol with Johns Hopkins University, Bloomberg School of Public Health;
- Completed technical optimization of the Wyss’s eRapid assay performance in relation to SARS-Cov-2 antibody detection at The Wyss Institute to align with the fastest antibody tests currently on market using clinical samples.

Glucose Key Developments

- Developing a clinical plan for regulatory submission and subsequent approval with Precision Medicine Architects, LLC;
- Initiated study for the salivary collection protocol with Johns Hopkins University, Bloomberg School of Public Health;
- Commenced global voice of customer survey with Precision Medicine Architects, LLC as part of the process to finalize product development of the device and usability;
- Further development of prototyping for middleware and smart phone application;
- Executed option agreement to acquire the rights to use, make, market, sell and offer to sell Products under the Intellectual Property Rights in the Glucose Field in the North American market for the Saliva Glucose Biosensor.

Initial public offering & share structure

On December 28, 2020, the Company closed its initial public offering (“IPO”) and sold 1,270,589 units, consisting of (a) one share of the Company’s common stock (or, at the purchaser’s election, one share of Series B Convertible Preferred Stock), (b) one Series A warrant (the “Series A Warrants”) to purchase one share of the Company’s common stock at an exercise price equal to \$8.50 per share, exercisable until the fifth anniversary of the issuance date, and (c) one Series B warrant (the “Series B Warrants”) to purchase one share of the Company’s common stock at an exercise price equal to \$17.00 per share, exercisable until the fifth anniversary of the issuance date and subject to certain adjustment and cashless exercise provisions. The public offering price of the shares sold in the IPO was \$17.00 per unit. In aggregate, the units issued in the offering generated \$17,732,448 in net proceeds, which amount is net of \$1,714,001 in underwriters’ discount and commissions, and \$2,153,564 in offering costs. The Company also issued to the underwriter an option, exercisable one or more times in whole or in part, to purchase up to 190,588 additional shares of common stock and/or Series A Warrants to purchase up to an aggregate of 190,588 shares of common stock and/or Series B Warrants to purchase up to an aggregate of 190,588 shares of common stock, in any combinations thereof, from us at the public offering price per security, less the underwriting discounts and commissions, for 45 days after the date of the IPO to cover over-allotments, if any (the “Over-Allotment Option”).

Upon the closing of the IPO, all shares of preferred stock then outstanding were automatically converted into 2,810,190 shares of common stock, and all convertible notes then outstanding were automatically converted into 710,548 shares of common stock.

Certain preferred shareholders were issued warrants that, following the Company’s completed IPO, allow the holder to acquire 2,736,675 shares of common stock at the IPO price during years two through three following the IPO. At the exercise date, the shareholder must hold for each warrant to be exercised, one underlying common share to exercise the option. The warrants are not transferable and apply to the number of shares that were subscribed for.

Accordingly, the share structure as of September 13, 2021 is as follows:

- 14,882,522 of Issued Common Stock
- 1,401,377 of Series A warrants exercisable at \$8.50
- 59,782 of Series B warrants exercisable at \$17.00 (subject to a cashless exercise provision)
- 63,529 of Warrants issued to the underwriter exercisable at \$18.70
- 2,736,675 of the Pre-IPO Warrants exercisable at \$8.50 (during year two through year three after the IPO)
- 3,000,000 Warrants issued to LSB D exercisable at \$17.00

Results of Operations:

Comparison of the Years Ended June 30, 2021 and 2020

Revenue

Government support income

Government support income increased by \$1,910,663 to \$1,980,484 from \$69,821 for the year ended June 30, 2021 compared to same period in 2020. This increase was primarily attributable to GBS Inc.’s subsidiary companies having received and entitlements to receive Research and Development tax incentives. The purpose of the grant is to incentivize companies with their research and development related activities and other COVID-19 related government support in the current period where the companies are located.

Shared service

Shared service revenue was zero and \$118,923 for the year ended June 30, 2021 and 2020, respectively. Shared service revenue is mainly attributable to the recovery of costs from related parties. There were no shared services in the current period.

Operating expenses

General and administrative expenses

General and administrative expenses increased by \$1,155,940 to \$3,359,065 from \$2,203,125 for the year ended June 30, 2021 compared to the same period in 2020. This increase was primarily driven by an increase in operational activities following completion of the IPO in the current period (December 2020).

As the Company's operating activities increase, we expect its general and administrative costs will include additional costs in overhead contribution, consultancy, as well as an increase in employee related costs associated with a higher headcount.

Development and regulatory expenses

Development and regulatory expenses increased by \$3,247,497 to \$3,835,703 from \$588,206 for the year ended June 30, 2021 compared to the same period in 2020. This increase is primarily driven by funding availability since completion of the IPO in December 2020 that has allowed the Company to progress on its milestones.

As the Company's operating activities increase, we expect its development and regulatory expenses to increase in future periods.

Prospectus and capital raising expenses

Prospectus and capital raising expenses increased by \$104,791 to \$359,198 from \$254,407 for the year ended June 30, 2021 as compared to the same period in 2020. This increase was attributable to final expenditures required by us in the first half of the current period to successfully complete our IPO in December 2020.

Other income and expenses

Interest expense

Interest expense increased by \$635,863 to \$1,093,608 from \$457,745 for the year ended June 30, 2021 as compared to the same period in 2020. This increase was attributable to the non-cash recognition of a beneficial conversion feature associated with convertible notes in the current period. This was partially offset by no interest expenses relating to convertible notes since the completion of the IPO due to their conversion into common stock.

Loss (income) from unconsolidated equity method investment

Loss from unconsolidated equity method investment changed by \$257,384 to a loss of \$135,692 for the year ended June 30, 2021 compared to a \$121,692 gain for the same period in 2020. This movement was attributable to the reduction in the carrying amount of its investment in BiosensX (North America) Inc.

Realized foreign exchange gain (loss)

Realized foreign exchange loss was \$271,225 for the year ended June 30, 2021 compared to zero for the same period in 2020. This increase was largely attributable to the unfavorable foreign exchange translations on capital raisings from AUD to USD.

Income tax (expense) benefit

There was no income tax expense for the year ended June 30, 2021 and 2020, respectively, as the Company has established a full valuation allowance for all of its deferred tax assets.

Other comprehensive income

Foreign currency translation gain/(loss)

Unrealized foreign currency translation loss increased by \$150,228 to \$297,309 from \$147,081 for the year ended June 30, 2021 and 2020, respectively. It is calculated based on the Company's unsettled transactions in currencies other than its functional currency.

Net loss

Net loss attributable to GBS Inc. increased by \$3,873,510 to \$7,037,286 from \$3,163,776 for the year ended June 30, 2021 compared to the same period in 2020. This increase is primarily driven by funding availability since completion of the IPO in December 2020. This has allowed the Company expand its operational activities in order to progress on its regulatory and development milestones.

Liquidity and Capital Resources

We use working capital and cash measures to evaluate the performance of our operations and our ability to meet our financial obligations. We define Working Capital as current assets less current liabilities. This measure should not be considered in isolation or as a substitute for any standardized measure under GAAP. This information is intended to provide investors with information about our liquidity. Other companies in our industry may calculate this measure differently than we do, limiting its usefulness as a comparative measure.

Since our inception, our operations have primarily been financed through the issuance of our common stock, redeemable convertible preferred stock and the incurrence of debt. As of June 30, 2021, we had \$12,573,685 in cash and cash equivalents and \$14,524,391 in working capital.

See “Initial public offering & share structure” herein for details about our IPO.

According to our management’s estimates, based on our budget and proposed schedules of development, approvals and organization, we believe, although there can be no assurances, we will have sufficient capital resources to enable us to continue to implement our business plan and remain in operation for at least 15 months. During this time, we expect to use the net proceeds available to us for the following purposes:

- to obtain regulatory approvals and establish manufacturing capacities necessary for marketing of the SGT;
- to market the SGT and establish a distribution network in the APAC Region; and
- for working capital and general corporate purposes.

We do not anticipate generating any revenue in the near future, until such time, if at all, the Company completes the development process of its products, including regulatory approvals, and thereafter, begins to commercialize and achieve substantial acceptance in the marketplace for the first of a series of products in its medical device portfolio. In addition, available resources may be consumed more rapidly than currently anticipated, and there can be no assurance that we will be successful in developing the SGT and generating sufficient revenue in the timeframe set forth above, or at all. We may be unable to meet our targets for regulatory approval and market launch, or we may be unable to generate anticipated amounts of revenue from sales of the system. We may also need additional funding for developing new products and services and for additional sales, marketing and promotional activities. Should this occur, we may need to seek additional capital earlier than anticipated.

In the event we require additional capital, there can be no assurances that we will be able to raise such capital on acceptable terms, or at all. Failure to generate sufficient revenues or raise additional capital through debt or equity financings, or through collaboration agreements, strategic alliances or marketing and distribution arrangements, could have a material adverse effect on our ability to meet our long-term liquidity needs and achieve our intended long-term business plan. Our failure to obtain such funding when needed could create a negative impact on our stock price or could potentially lead to a reduction in our operations or the failure of our company.

Extended Transition Period for “Emerging Growth Companies”

We have elected to use the extended transition period for complying with new or revised accounting standards under Section 102(b)(1) of the JOBS Act. This election allows us to delay the adoption of new or revised accounting standards that have different effective dates for public and private companies until those standards apply to private companies. As a result of this election, our financial statements may not be comparable to companies that comply with public company effective dates. Because our financial statements may not be comparable to companies that comply with public company effective dates, investors may have difficulty evaluating or comparing our business, performance or prospects in comparison to other public companies, which may have a negative impact on the value and liquidity of our common stock.

Off-Balance Sheet Arrangements

As of June 30, 2021, we do not have any off-balance-sheet arrangements that have, or are reasonably likely to have, a current or future effect on our results of operations or financial condition, including, and without limitation, such considerations as liquidity and capital resources.

Critical Accounting Estimates

The preparation of our consolidated financial statements in conformity with GAAP requires management to make judgments, estimates and assumptions that impact the amounts reported in our consolidated financial statements and accompanying notes that are not readily apparent from other sources. The estimates and associated assumptions are based on historical experience and other factors that are considered relevant. Actual results may differ from these estimates.

The estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognized in the period in which the estimate is revised, if the revision affects only that period, or in the period of the revision and future periods, if the revision affects both current and future periods.

Note 3 to the consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K, and incorporated herein by reference, describes the Company's accounting policies. The following discussion should be read in conjunction with Note 3, as it presents uncertainties involved in applying the accounting policies and provides insight into the quality of management's estimates and variability in the amounts recorded for these critical accounting estimates. While all accounting policies impact the consolidated financial statements, certain policies may be viewed to be critical. Management believes that the accounting policies which involve more significant judgments and estimates used in the preparation of our consolidated financial statements include research and development tax refunds.

Research and Development (R & D) tax refund

The Company measures the research and development grant income and receivable by taking into account the time spent by employees on eligible research and development activities and research and development costs incurred to external service providers. The research and development tax refund receivable is recognized as the company believes that it probable that the amount will be recovered in full through a future claim.

Recently issued Accounting Pronouncements

For the impact of recently issued accounting pronouncements on the Company's consolidated financial statements, see Note 3 to the consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K and incorporated herein by reference.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information otherwise required under this item.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

The consolidated financial statements required pursuant to this item are included in Part IV, Item 15 of this Annual Report on Form 10-K, beginning on page F-1, and incorporated herein by reference.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURES.

None.

ITEM 9A. CONTROLS AND PROCEDURES.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) as of the end of the period covered by this Annual Report on Form 10-K, and have concluded that, based on such evaluation, our disclosure controls and procedures were not effective due to the material weakness in our internal control over financial reporting as of June 30, 2021 as described below.

Notwithstanding the conclusion that our disclosure controls and procedures were not effective as of the end of the period covered by this report, we believe that our consolidated financial statements and other information contained in this annual report on Form 10-K present fairly, in all material respects, our business, financial condition and results of operations for the interim periods presented.

Material Weakness

The Company completed the IPO in December 2020. Prior to the IPO, the Company was a private corporation with limited accounting personnel and other supervisory resources necessary to adequately execute its accounting processes and address its internal controls over financial reporting requirements. As a result, previously existing internal controls are no longer sufficient, and the Company is in the process of updating these controls. The design and implementation of internal control over financial reporting for the Company's post-IPO has required and will continue to require significant time and resources from management and other personnel.

As part of this updating process, our management identified a material weakness in its internal control over financial reporting. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. The material weakness identified relates to the fact that the Company has not yet designed and maintained an effective control environment commensurate with its financial reporting requirements, including a) has not yet completed the formally documented policies and procedures with respect to the review, supervision and monitoring of the Company's accounting and reporting functions, b) lack of evidence to support the performance of controls and the adequacy of review procedures, including the completeness and accuracy of information used in the performance of controls and c) as an emerging growth company we currently have limited accounting personnel and other supervisory resources necessary to adequately execute the Company's accounting processes and address its internal controls over financial reporting requirements.

Remediation Plan

Management is committed to continuing with the steps necessary to remediate the control deficiencies that constituted the above material weakness. Since the IPO, we made the following enhancements to our control environment:

- a. We added accounting and finance personnel to provide additional individuals to allow for segregation of duties in the preparation and review of schedules, calculations, and journal entries that support financial reporting, to provide oversight, structure and reporting lines, and to provide additional review over our disclosures;
- b. We enhanced our controls to improve the preparation and review over complex accounting measurements, and the application of GAAP to significant accounts and transactions, and our financial statement disclosures; and,
- c. We are in the process of engaging outside consultants to assist us in our evaluation of the design, implementation, and documentation of internal controls that address the relevant risks, and that provide for appropriate evidence of performance of our internal controls (including completeness and accuracy procedures).

Under the direction of the audit committee of the board of directors, management will continue to take measures to remediate the material weakness in 2021. As such, we will continue to enhance corporate oversight over process-level controls and structures to ensure that there is appropriate assignment of authority, responsibility, and accountability to enable remediation of our material weakness. We believe that our remediation plan will be sufficient to remediate the identified material weakness and strengthen our internal control over financial reporting.

As we continue to evaluate, and work to improve, our internal control over financial reporting, management may determine that additional measures to address control deficiencies or modifications to the remediation plan are necessary.

Inherent Limitation on the Effectiveness of Internal Controls

The effectiveness of any system of internal control over financial reporting, including ours, is subject to inherent limitations, including the exercise of judgment in designing, implementing, operating, and evaluating the controls and procedures, and the inability to eliminate misconduct completely. Accordingly, in designing and evaluating the disclosure controls and procedures, management recognizes that any system of internal control over financial reporting, including ours, no matter how well designed and operated, can only provide reasonable, not absolute assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints, and that management is required to apply its judgment in evaluating the benefits of possible controls and procedures relative to their costs. Moreover, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. We intend to continue to monitor and upgrade our internal controls as necessary or appropriate for our business, but cannot assure you that such improvements will be sufficient to provide us with effective internal control over financial reporting

Management's Report on Internal Control Over Financial Reporting

This Annual Report on Form 10-K does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of our independent registered public accounting firm due to a transition period established by the rules of the SEC for newly public companies.

Changes in Internal Control Over Financial Reporting

There have been no changes to the Company's internal controls over financial reporting (as defined in Rules 13a-15(f) and 15d 15(f) under the Exchange Act) during the most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION.

On June 30, 2021, the Company was awarded a \$4.7 million (excluding GST/VAT), Australian Federal Government scientific grant to fund the build out of a Biosensor manufacturing facility. This project has been identified as one of six National Manufacturing Priorities identified by the Government under Modern Manufacturing Strategy (MMS). The Medical Products Priority Grant, from the Australian Federal Government's Department of Industry, Science, Energy and Resources' Modern Manufacturing Initiative will support the establishment of an Australian high tech medical device manufacturing facility to commence scaled production of the Printable Organic Electronic Biosensor technology for the APAC region. Amounts will be paid under this grant upon GBS achieving certain deliverables

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTION

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by Item 10 will be included in the Registrant's definitive proxy statement to be filed pursuant to Section 14(a) of the Exchange Act of 1934 and is incorporated herein by reference.

ITEM 11. EXECUTIVE COMPENSATION

The information required by Item 11 will be included in the Registrant's definitive proxy statement to be filed pursuant to Section 14(a) of the Exchange Act of 1934 and is incorporated herein by reference.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED SHAREHOLDER MATTERS

The information required by Item 12 will be included in the Registrant's definitive proxy statement to be filed pursuant to Section 14(a) of the Exchange Act and is incorporated herein by reference.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by Item 13 will be included in the Registrant's definitive proxy statement to be filed pursuant to Section 14(a) of the Exchange Act and is incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTANTING FEES AND SERVICES

The information required by Item 14 will be included in the Registrant's definitive proxy statement to be filed pursuant to Section 14(a) of the Exchange Act and is incorporated herein by reference.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENTS SCHEDULES

(a) Documents filed as part of this Annual Report on Form 10-K:

- (1) Financial Statements. The financial statements required to be included in this Annual Report on Form 10-K are listed in the Table of Contents to Financial Statements appearing immediately after the signature page of this Form 10-K and are included herein by reference.
- (2) Financial Statement Schedules. All schedules are omitted because they are not applicable, or the required information is shown in the Financial Statements or notes thereto.
- (3) See attached Exhibit Index of this Annual Report on Form 10-K.

(b) The following exhibits are provided as required by Item 601 of Regulation S-K

Exhibit No.	Description
3.1	<u>Amended and Restated Certificate of Incorporation ((incorporated by reference to Exhibit 3.4 to the Company's Amended Registration Statement on Form S-1/A (File No. 333-232557) filed with the Commission on December 21, 2020)</u>
3.2	<u>Amended and Restated By-laws. ((incorporated by reference to Exhibit 3.2 to the Company's Amended Registration Statement on Form S-1/A (File No. 333-232557) filed with the Commission on October 13, 2020)</u>
3.3.	<u>Certificate of Designation of Series B Preferred Stock ((incorporated by reference to Exhibit 3.3 to the Company's Amended Registration Statement on Form S-1/A (File No. 333-232557) filed with the Commission on October 20, 2020.)</u>
4.1	<u>Specimen Common Stock Certificate ((incorporated by reference to Exhibit 4.1 to the Company's Amended Registration Statement on Form S-1/A (File No. 333-232557) filed with the Commission on September 19, 2019.)</u>
4.2	<u>Form of Series A Warrant ((incorporated by reference to Exhibit 4.2 to the Company's Amended Registration Statement on Form S-1/A (File No. 333-232557) filed with the Commission on October 20, 2020.)</u>
4.3	<u>Form of Series B Warrant ((incorporated by reference to Exhibit 4.3 to the Company's Amended Registration Statement on Form S-1/A (File No. 333-232557) filed with the Commission on October 20, 2020.)</u>
4.4	<u>Form of Warrant Agency Agreement ((incorporated by reference to Exhibit 4.4 to the Company's Amended Registration Statement on Form S-1/A (File No. 333-232557) filed with the Commission on October 20, 2020.)</u>
4.5	<u>Form LSBW Warrant ((incorporated by reference to Exhibit 4.6 to the Company's Amended Registration Statement on Form S-1/A (File No. 333-232557) filed with the Commission on December 21, 2020)</u>

- 4.6# [Description of Registrant’s Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934.](#)
- 10.1* [2019 Incentive Equity Plan \(\(incorporated by reference to Exhibit 10.1 to the Company’s Amended Registration Statement on Form S-1/A \(File No. 333-232557\) filed with the Commission on August 2, 2019\)](#)
- 10.2 [Amended and Restated License Agreement between the Company and Life Science Biosensor Diagnostics Pty Ltd. \(\(incorporated by reference to Exhibit 10.2 to the Company’s Amended Registration Statement on Form S-1/A \(File No. 333-232557\) filed with the Commission on October 13, 2020\)](#)
- 10.3 [Master Services Agreement between the Company and IQ3Corp Limited \(\(incorporated by reference to Exhibit 10.3 to the Company’s Amended Registration Statement on Form S-1/A \(File No. 333-232557\) filed with the Commission on August 2, 2019\)](#)
- 10.4 [Medical Affairs Services Agreement between the Company and Clinical Research Corporation \(\(incorporated by reference to Exhibit 10.4 to the Company’s Amended Registration Statement on Form S-1/A \(File No. 333-232557\) filed with the Commission on August 2, 2019\)](#)
- 10.5* [Form of Employment Agreement between the Company and Mr. Simeonidis \(\(incorporated by reference to Exhibit 10.5 to the Company’s Amended Registration Statement on Form S-1/A \(File No. 333-232557\) filed with the Commission on August 21, 2019\)](#)
- 10.6* [Form of Employment Agreement between the Company and Dr. Becker \(\(incorporated by reference to Exhibit 10.6 to the Company’s Amended Registration Statement on Form S-1/A \(File No. 333-232557\) filed with the Commission on August 2, 2019\)](#)
- 10.7* [Form of Employment Agreement between the Company and Mr. Sakiris \(\(incorporated by reference to Exhibit 10.7 to the Company’s Amended Registration Statement on Form S-1/A \(File No. 333-232557\) filed with the Commission on August 21, 2019\)](#)
- 10.8 [Form of Lock-Up Agreement \(included in Exhibit 1.1 to Form of Underwriting Agreement.\) \(\(incorporated by reference to Exhibit 1.1 to the Company’s Amended Registration Statement on Form S-1/A \(File No. 333-232557\) filed with the Commission on October 20, 2020.\)](#)
- 10.9 [Letter of Financial Assistance from The iQ Group Global Ltd. \(\(incorporated by reference to Exhibit 10.2 to the Company’s Amended Registration Statement on Form S-1/A \(File No. 333-232557\) filed with the Commission on October 13, 2020\)](#)
- 10.10 [Letter of Financial Assistance from iQX Limited. \(\(incorporated by reference to Exhibit 10.10 to the Company’s Amended Registration Statement on Form S-1/A \(File No. 333-232557\) filed with the Commission on October 13, 2020\)](#)

- 10.11 [Form of Letter of Equity Support from iQnovate Limited \(\(incorporated by reference to Exhibit 10.11 to the Company's Amended Registration Statement on Form S-1/A \(File No. 333-232557\) filed with the Commission on August 6, 2020\)](#)
- 10.12 [Form of Letter of Equity Support from iQX Limited \(\(incorporated by reference to Exhibit 10.12 to the Company's Amended Registration Statement on Form S-1/A \(File No. 333-232557\) filed with the Commission on August 6, 2020\)](#)
- 10.13 [Technology License Agreement between the Company and Life Science Biosensor Diagnostics Pty Ltd. \(\(incorporated by reference to Exhibit 10.13 to the Company's Amended Registration Statement on Form S-1/A \(File No. 333-232557\) filed with the Commission on October 13, 2020\)](#)
- 10.14 [Material Transfer Agreement between Life Science Biosensor Diagnostics Pty Ltd and Wyss Institute for Biologically Inspired Engineering \(\(incorporated by reference to Exhibit 10.14 to the Company's Amended Registration Statement on Form S-1/A \(File No. 333-232557\) filed with the Commission on October 13, 2020\)](#)
- 10.15 [Form of Exchange Agreement \(\(incorporated by reference to Exhibit 10.15 to the Company's Amended Registration Statement on Form S-1/A \(File No. 333-232557\) filed with the Commission on December 21, 2020\)](#)
- 10.16 [Form of Registration Rights Agreement \(\(incorporated by reference to Exhibit 10.16 to the Company's Amended Registration Statement on Form S-1/A \(File No. 333-232557\) filed with the Commission on December 21, 2020\)](#)
- 10.17 [Form of Purchase and Assignment Agreement \(\(incorporated by reference to Exhibit 10.16 to the Company's Amended Registration Statement on Form S-1/A \(File No. 333-232557\) filed with the Commission on December 21, 2020\)](#)
- 10.18 [Option Agreement \(\(incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Commission on April 2, 2021\).](#)
- 14.1 [Code of Ethics \(\(incorporated by reference to Exhibit 14.1 to the Company's Amended Registration Statement on Form S-1/A \(File No. 333-232557\) filed with the Commission on August 6, 2020\)](#)
- 21.1# [List of Subsidiaries](#)
- 31.1# [Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.](#)

- 31.2# [Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.](#)
- 32.1# [Certification of the Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.](#)
- 32.2# [Certification of the Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.](#)
- 101.INS# XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document
- 101.SCH# XBRL Taxonomy Extension Schema Document.
- 101.CAL# XBRL Taxonomy Extension Calculation Linkbase Document.
- 101.DEF# XBRL Taxonomy Extension Definition Linkbase Document.
- 101.LAB# XBRL Taxonomy Extension Label Linkbase Document.
- 101.PRE # XBRL Taxonomy Extension Presentation Linkbase Document.
- 104# Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)

***Indicates management contract or compensatory plan.**

Filed herewith.

ITEM 16. FORM 10-K SUMMARY.

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Exchange Act of 1934, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

GBS Inc.

Date: September 15, 2021

By: /s/ Harry Simeonidis
HARRY SIMEONIDIS
CHIEF EXECUTIVE OFFICER AND PRESIDENT
(Principal Executive Officer)

Date: September 15, 2021

By: /s/ Spiro Sakiris
SPIRO SAKIRIS
CHIEF FINANCIAL OFFICER
(Principal Financial Officer)

Pursuant to the requirements of the Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Harry Simeonidis</u> Harry Simeonidis	Chief Executive Officer, President and Director (Principal Executive Officer)	September 15, 2021
<u>/s/ Spiro Sakiris</u> Spiro Sakiris	Chief Financial Officer (Principal Financial Officer)	September 15, 2021
<u>/s/ Steven Boyages</u> Dr. Steven Boyages	Director	September 15, 2021
<u>/s/ Jonathan Sessler</u> Prof. Jonathan Sessler	Director	September 15, 2021
<u>/s/ Tom Parmakellis</u> Dr. Tom Parmakellis	Director	September 15, 2021
<u>/s/ Jonathan Hurd</u> Jonathan Hurd	Director	September 15, 2021
<u>/s/ Leon Kempler</u> Leon Kempler	Director	September 15, 2021
<u>/s/ George Margelis</u> Dr. George Margelis	Director	September 15, 2021
<u>/s/ Lawrence Fisher</u> Lawrence Fisher	Director	September 15, 2021
<u>/s/ Christopher Towers</u> Christopher Towers	Director	September 15, 2021

GBS Inc.
Index to the Consolidated Financial Statements

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Report of Independent Registered Public Accounting Firm

Shareholders and Board of Directors
GBS Inc.
New York, New York

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of GBS Inc. (the “Company”) as of June 30, 2021 and 2020, the related consolidated statements of operations and comprehensive loss, changes in shareholders’ equity, and cash flows for each of the two years in the period ended June 30, 2021, and the related notes (collectively referred to as the “consolidated financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at June 30, 2021 and 2020, and the results of its operations and its cash flows for each of the two years in the period ended June 30, 2021, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (“PCAOB”) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ BDO Audit Pty Ltd

We have served as the Company’s auditor since 2017.
Sydney, Australia
September 15, 2021

GBS Inc.
Consolidated Balance Sheets

	June 30, 2021	June 30, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 12,573,685	\$ 427,273
Deferred charges	-	1,863,613
Grant receivable, current portion	2,098,884	-
Research and development tax incentive receivable	1,025,455	-
Other current assets	2,509,017	49,062
Total current assets	<u>18,207,041</u>	<u>2,339,948</u>
Investment in affiliate	-	135,692
Grant receivable, net of current portion	3,148,328	-
Other non-current assets	504,000	-
TOTAL ASSETS	<u>\$ 21,859,369</u>	<u>\$ 2,475,640</u>
LIABILITIES AND SHAREHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable and accrued expenses	\$ 1,570,443	\$ 787,469
Related party payables	13,323	1,769,293
Current portion of deferred grant income	2,098,884	-
Convertible notes payable	-	5,133,706
Total current liabilities	<u>3,682,650</u>	<u>7,690,468</u>
Employee benefit liabilities	21,770	-
Long-term deferred grant income	3,148,328	-
Total liabilities	<u>6,852,748</u>	<u>7,690,468</u>
Commitments and contingencies (Note 11)	-	-
Shareholders' equity (deficit):		
Preferred stock, \$0.01 par value, 10,000,000 shares authorized, 1,300,000 and 2,370,891 shares issued and outstanding at June 30, 2021 and 2020, respectively	13,000	23,709
Common stock, \$0.01 par value, 100,000,000 shares authorized, 13,582,122 and 8,630,000 shares issued and outstanding at June 30, 2021 and 2020, respectively	135,821	86,300
Additional paid-in capital	38,440,089	10,899,942
Accumulated deficit	(22,869,803)	(15,832,517)
Accumulated other comprehensive loss	(661,260)	(363,951)
Total consolidated group equity (deficit)	<u>15,057,847</u>	<u>(5,186,517)</u>
Non-controlling interest	(51,226)	(28,311)
Total shareholders' equity (deficit)	<u>15,006,621</u>	<u>(5,214,828)</u>
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	<u>\$ 21,859,369</u>	<u>\$ 2,475,640</u>

The accompanying notes are an integral part of these consolidated financial statements.

GBS Inc.
Consolidated Statements of Operations and Other Comprehensive Loss

	Year Ended June 30,	
	2021	2020
Revenues:		
Other income:		
Government support income	\$ 1,980,484	\$ 69,821
Shared services	-	118,923
Total revenues	<u>1,980,484</u>	<u>188,744</u>
Operating expenses:		
General and administrative expenses	3,359,065	2,203,125
Development and regulatory approval expenses	3,835,703	588,206
Prospectus and capital raising expenses	359,198	254,407
Total operating expenses	<u>7,553,966</u>	<u>3,045,738</u>
Loss from operations	(5,573,482)	(2,856,994)
Other (expense) income:		
Interest expense	(1,093,608)	(457,745)
(Loss) income from unconsolidated equity method investment	(135,692)	121,692
Realized foreign exchange loss	(271,225)	-
Interest income	13,806	97
Total other expense	<u>(1,486,719)</u>	<u>(335,956)</u>
Loss before income taxes	(7,060,201)	(3,192,950)
Income taxes	-	-
Net loss	(7,060,201)	(3,192,950)
Net loss attributable to non-controlling interest	(22,915)	(29,174)
Net loss attributable to GBS, Inc.	<u>\$ (7,037,286)</u>	<u>\$ (3,163,776)</u>
Other comprehensive loss, net of tax:		
Foreign currency translation loss	\$ (297,309)	\$ (147,081)
Total other comprehensive loss	<u>(297,309)</u>	<u>(147,081)</u>
Comprehensive loss	(7,357,510)	(3,340,031)
Comprehensive loss attributable to non-controlling interest	(22,915)	(29,174)
Comprehensive loss attributable to GBS, Inc.	<u>\$ (7,334,595)</u>	<u>\$ (3,310,857)</u>
Net loss per share, basic and diluted	\$ (0.68)	\$ (0.37)
Weighted average shares outstanding, basic and diluted	10,414,886	8,510,329

The accompanying notes are an integral part of these consolidated financial statements.

GBS Inc.
Consolidated Statements of Changes in Shareholders' Equity

	<u>Preferred stock</u>		<u>Common stock</u>		<u>Additional paid in capital</u>	<u>Accumulated deficit</u>	<u>Other comprehensive (loss) income</u>	<u>Non-controlling interest</u>	<u>Total shareholders' equity (deficit)</u>
	<u>Shares</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>					
Balance, June 30, 2019	2,064,884	\$ 20,649	8,510,000	\$ 85,100	\$ 8,164,804	\$ (12,668,741)	\$ (216,870)	\$ 637,919	\$ (3,977,139)
Reclassification of non-controlling interest	-	-	-	-	637,056	-	-	(637,056)	-
Balance, June 30, 2019	2,064,884	20,649	8,510,000	85,100	8,801,860	(12,668,741)	(216,870)	863	(3,977,139)
Deemed dividend	-	-	-	-	(976,308)	-	-	-	(976,308)
Issuance of common shares	-	-	120,000	1,200	898,800	-	-	-	900,000
Issuance of convertible preferred shares	306,007	3,060	-	-	2,291,992	-	-	-	2,295,052
Issuance costs for common and preferred shares	-	-	-	-	(116,402)	-	-	-	(116,402)
Foreign currency translation loss	-	-	-	-	-	-	(147,081)	-	(147,081)
Net loss	-	-	-	-	-	(3,163,776)	-	(29,174)	(3,192,950)
Balance, June 30, 2020	2,370,891	23,709	8,630,000	86,300	10,899,942	(15,832,517)	(363,951)	(28,311)	(5,214,828)
Issuance of convertible preferred shares	439,299	4,393	-	-	3,290,352	-	-	-	3,294,745
Issuance of common stock at initial public offering	-	-	1,270,589	12,706	21,587,307	-	-	-	21,600,013
Issuance cost of common stock at initial public offering	-	-	-	-	(3,867,565)	-	-	-	(3,867,565)
Cancellation of common stock in exchange for preferred shares	3,000,000	30,000	(3,000,000)	(30,000)	-	-	-	-	-
Conversion of convertible notes into common stock at initial public offering	-	-	710,548	7,105	5,126,601	-	-	-	5,133,706
Conversion of convertible preferred shares into common stock at initial public offering	(2,810,190)	(28,102)	2,810,190	28,102	-	-	-	-	-
Beneficial conversion feature	-	-	-	-	905,948	-	-	-	905,948
Series A warrants exercised to purchase common shares	-	-	59,800	598	507,702	-	-	-	508,300
Series B warrants exercised to purchase common shares	-	-	1,400,995	14,010	(14,010)	-	-	-	-
Series A and B warrants acquired	-	-	-	-	3,812	-	-	-	3,812
Conversion of convertible preferred shares into common stock	(1,700,000)	(17,000)	1,700,000	17,000	-	-	-	-	-
Foreign currency translation loss	-	-	-	-	-	-	(297,309)	-	(297,309)
Net loss	-	-	-	-	-	(7,037,286)	-	(22,915)	(7,060,201)
Balance, June 30, 2021	<u>1,300,000</u>	<u>\$ 13,000</u>	<u>13,582,122</u>	<u>\$ 135,821</u>	<u>\$ 38,440,089</u>	<u>\$ (22,869,803)</u>	<u>\$ (661,260)</u>	<u>\$ (51,226)</u>	<u>\$ 15,006,621</u>

The accompanying notes are an integral part of these consolidated financial statements.

GBS Inc.
Consolidated Statements of Cash Flows

	Year Ended June 30,	
	2021	2020
Cash flows from operating activities:		
Net loss	\$ (7,060,201)	\$ (3,192,950)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash loss on foreign currency translation, net	(271,225)	-
(Profit)/Loss on investment in affiliate	135,692	(121,692)
Contingent beneficial conversion feature on convertible notes	905,948	-
Money received for which preference shares were issued after year-end	-	225,000
Non-cash other operating activities	(66,055)	(36,048)
Changes in operating assets and liabilities:		
Other receivables	-	118,056
Research and development tax incentive receivable	(1,025,455)	-
Other current assets	(2,459,955)	99,279
Other non-current assets	(504,000)	-
Accounts payable	782,974	(350,200)
Accounts payable - related party	(1,755,970)	2,759,937
Other long-term liabilities	21,770	-
Net cash used in operating activities	(11,296,477)	(498,618)
Cash flows from investing activities:		
Investment in affiliate	-	(14,000)
Net cash used in investing activities	-	(14,000)
Cash flows from financing activities:		
Proceeds from issuance of warrants	3,812	-
Proceeds from warrant holders for common shares	508,300	-
Proceeds from issuance of preferred stock	3,294,745	1,001,250
Payment to convertible note holders	-	(150,986)
Proceeds from initial public offering	21,600,013	-
Payment of equity issuance costs	(2,003,952)	(116,402)
Net cash provided by financing activities	23,402,918	733,862
Effect of foreign exchange rates on cash and cash equivalents	39,971	8,089
Increase in cash and cash equivalents	12,146,412	229,333
Cash and cash equivalents, beginning of period	427,273	197,940
Cash and cash equivalents, end of period	<u>\$ 12,573,685</u>	<u>\$ 427,273</u>
Non-cash investing and financing activities		
Reclassification of deferred charges to additional paid in capital upon completion of initial public offering	\$ 1,863,613	\$ -
Conversion of notes to common shares at initial public offering	5,133,706	-
Cancellation of common stock in exchange for preferred shares	30,000	-
Conversion of preferred shares into common shares	45,102	-
Preference shares issued through offsetting the related party loans	-	1,102,717
Non-cash deemed dividend	-	(976,000)
Common stock issued through offsetting of related party loans	-	900,000
Supplemental disclosure of cash flow information:		
Cash paid for income taxes	\$ -	\$ -
Cash paid for interest	185,301	327,311

The accompanying notes are an integral part of these consolidated financial statements.

GBS Inc.
Notes to the Consolidated Financial Statements

NOTE 1. ORGANIZATION AND DESCRIPTION OF THE BUSINESS

GBS Inc. and its wholly owned subsidiary, GBS Operations Inc. were formed on December 5, 2016 under the laws of the state of Delaware. Glucose Biosensor Systems (Greater China) Pty Ltd (“GBSPL”) was formed on August 4, 2016 under the laws of New South Wales, Australia and was renamed to GBS (APAC) Pty Ltd on October 14, 2020. Glucose Biosensor Systems (Japan) Pty Ltd and Glucose Biosensor Systems (APAC) Pty Ltd were formed under the laws of New South Wales, Australia on February 22, 2017 and February 23, 2017 respectively. These companies (collectively, the “Company”) were formed to provide a non-invasive, pain free innovation to make it easier for people to manage diabetes using the Company’s Saliva Glucose Biosensor (“SGB” and, together with the software app that interfaces the SGB with the Company’s digital information system, the “SGT”).

We are a biosensor diagnostic technology company operating across the Asia-Pacific Region (“APAC”) Region and an interest in the USA Region with the biosensor platform comprising of biochemistry, immunology, tumor markers, hormones, and nucleic acid diagnostic modalities, and worldwide with our COV2 test. We were incorporated under the laws of Delaware on December 5, 2016. Our headquarters are located in New York, New York.

Our objective is to introduce and launch initially the Saliva Glucose Biosensor (referred to as the “SGB”), the diagnostic test that stems from the Biosensor Platform that we license, in our regions and the COV2 test globally. This will be followed by developing the platform to its full capacity testing across the diagnostic modalities of Immunology, Hormones, Chemistry, Tumor markers and Nucleic Acid tests.

GBS Inc. is a 42.6% (as of June 30 2021) owned (by voting rights) affiliate of Life Science Biosensor Diagnostics Pty Ltd (“LSBD”), an Australian company that owns the worldwide intellectual property rights to the biosensor platform from University of Newcastle, Australia. LSBD has licensed to the Company that technology to introduce and launch the platform in the APAC.

Initial public offering

On December 28, 2020, the Company closed its initial public offering (“IPO”) and sold 1,270,589 units, consisting of (a) one share of the Company’s common stock (or, at the purchaser’s election, one share of Series B Convertible Preferred Stock), (b) one Series A warrant (the “Series A Warrants”) to purchase one share of the Company’s common stock at an exercise price equal to \$8.50 per share, exercisable until the fifth anniversary of the issuance date, and (c) one Series B warrant (the “Series B Warrants”) to purchase one share of the Company’s common stock at an exercise price equal to \$17.00 per share, exercisable until the fifth anniversary of the issuance date and subject to certain adjustment and cashless exercise provisions. The public offering price of the shares sold in the IPO was \$17.00 per unit. In aggregate, the units issued in the offering generated \$17,732,448 in net proceeds, which amount is net of \$1,714,001 in underwriters’ discount and commissions, and \$2,153,564 in offering costs. Offering costs include underwriters’ warrants to acquire up to 63,529 shares with an exercise price of \$18.70 per share, exercisable until the fifth anniversary of the issuance date. The Company also issued to the underwriter an option, exercisable one or more times in whole or in part, to purchase up to 190,588 additional shares of common stock and/or Series A Warrants to purchase up to an aggregate of 190,588 shares of common stock and/or Series B Warrants to purchase up to an aggregate of 190,588 shares of common stock, in any combinations thereof, from us at the public offering price per security, less the underwriting discounts and commissions, for 45 days after the date of the IPO to cover over-allotments, if any (the “Over-Allotment Option”).

Upon the closing of the IPO, all shares of preferred stock then outstanding were automatically converted into 2,810,190 shares of common stock, and all convertible notes then outstanding were automatically converted into 710,548 shares of common stock.

Pre-IPO preferred shareholders were issued warrants following the Company's completed IPO, that allows the holder to acquire 2,736,675 shares of common stock at the IPO price during year two through to year three following the completion of the IPO. At exercise date, the shareholder must hold, for each warrant to be exercised, the underlying common share to exercise the warrant. The warrants are not transferable and apply to the number of shares that were subscribed for.

NOTE 2. LIQUIDITY

The Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 205-40, *Presentation of Financial Statements - Going Concern* (ASC 205-40) requires management to assess an entity's ability to continue as a going concern within one year of the date of the financial statements are issued. In each reporting period, including interim periods, an entity is required to assess conditions known and reasonably knowable as of the financial statement issuance date to determine whether it is probable an entity will not meet its financial obligations within one year from the financial statement issuance date. Substantial doubt about an entity's ability to continue as a going concern exists when conditions and events, considered in the aggregate, indicate it is probable the entity will be unable to meet its financial obligations as they become due within one year after the date the financial statements are issued.

The Company is an emerging growth company and has not generated any revenues to date. As such, the Company is subject to all of the risks associated with emerging growth companies. Since inception, the Company has incurred losses and negative cash flows from operating activities. The Company does not expect to generate positive cash flows from operating activities in the near future until such time, if at all, the Company completes the development process of its products, including regulatory approvals, and thereafter, begins to commercialize and achieve substantial acceptance in the marketplace for the first of a series of products in its medical device portfolio.

The Company incurred a net loss of \$7,037,286 for the year ended June 30, 2021 (net loss of \$3,163,776 for the year ended June 30, 2020). At June 30, 2021, the Company has shareholders' equity of \$15,006,621, working capital of \$14,524,391, and an accumulated deficit of \$22,869,803.

In the near future, the Company anticipates incurring operating losses and does not expect to experience positive cash flows from operating activities and may continue to incur operating losses until it completes the development of its products and seeks regulatory approvals to market such products.

The Company's consolidated financial statements have been prepared on a going concern basis which contemplates the realization of assets and satisfaction of liabilities and commitments in the normal course of business. The consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities should the Company be unable to continue as a going concern.

As a result of the Company's initial public offering (see Note 1), the Company believes it has sufficient working capital to finance its operations for the next twelve months, as such, these financial statements are prepared on the going concern basis.

NOTE 3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of presentation

The consolidated financial statements of the Company have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") and the rules and regulations of the Securities and Exchange Commission ("SEC") as of June 30, 2021 and 2020.

Principles of consolidation

These consolidated financial statements as of and for the years ended June 30, 2021 and 2020 include the accounts of the Company, all wholly-owned and majority-owned subsidiaries in which the Company has a controlling voting interest. Investments in affiliates where the Company does not exert a controlling financial interest are not consolidated. All significant intercompany transactions and balances have been eliminated upon consolidation.

Equity offering costs

The Company complies with the requirements of ASC 340 with regards to offering costs. Prior to the completion of an offering, offering costs were capitalized as deferred offering costs on the balance sheet. The deferred offering costs were charged to shareholders' equity (deficit) upon the completion of an offering. Offering costs amounting to \$nil were capitalized as of June 30, 2021 (June 30, 2020: \$1,863,613). This was a result of the balance being charged to shareholders' equity with completion of its initial public offering in December 2020.

Use of estimates

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements, and the reported amounts of revenue and expenses during the reporting period. Actual results could materially differ from those estimates.

Reclassifications

Certain reclassifications have been made to prior periods to conform to current period presentation within the consolidated statements of operations and other comprehensive loss.

In addition to the above, in the comparative period (FY 2020), management determined that certain transactions involving the issuance of shares of its subsidiary that occurred during the prior year should have resulted in an adjustment to non-controlling interest (NCI) and Additional Paid-in-Capital (APIC) to reflect the difference between the fair value of the consideration received and the book value of NCI involving these changes in ownership. As a result, the Company increased its prior year APIC with an offsetting reduction to NCI of \$637,056. Management concluded that this reclassification was not meaningful to the Company's financial position for the prior year, and as such, this change was recorded in the consolidated balance sheets and statements of shareholder's equity in the first quarter of the comparative period (FY 2020) as an out-of-period adjustment.

Revenue recognition

Revenue from contracts with customers is recognized when, or as, the Company satisfies its performance obligations by delivering the promised goods or service deliverables to the customers. A good or service deliverable is transferred to a customer when, or as, the customer obtains control of that good or service deliverable. The Company currently does not generate any revenue.

Deferred grant income

On June 30 2021, GBS executed a definitive grant agreement with the Australian Government to assist with building a manufacturing facility. The grant has a total value of up to \$5.24 million upon the completion of deliverables by GBS. Proceeds from the grant will be used primarily to reimburse GBS for costs incurred in the construction of the manufacturing facility.

Accounting for the grant does not fall under ASC 606, Revenue from Contracts with Customers, as the Australian Government will not benefit directly from our manufacturing facility. As there is no authoritative guidance under U.S. GAAP on accounting for grants to for-profit business entities, we applied International Accounting Standards 20 ("IAS 20"), *Accounting for Government Grants and Disclosure of Government Assistance* by analogy when accounting for the Australian Government grant to GBS.

Under IAS 20, government grant is initially recognized when there is reasonable assurance the conditions of the grant will be met and the grant will be received. As of the June 30, 2021, management concluded there is reasonable assurance the grant conditions will be met and all milestone payment received. The total grant value of \$5.24 million has been recognized as both a grant receivable and deferred grant income on the Consolidated Balance Sheets.

After initial recognition, under IAS 20, government grants are recognized in earnings on a systematic basis in a manner that mirrors the manner in which the Company recognizes the underlying costs for which the grant is intended to compensate. Further, IAS 20 permits for recognition in earnings either separately under a general heading such as other income, or as a reduction of the cost of the asset. The Company has elected to recognize government grant income separately within other income. Accordingly, the deferred income related to the construction of the manufacturing facility will be amortized over the period of depreciation for the related factory as other income.

Research and Development (R & D) tax refund

The Company measures the research and development grant income and receivable by considering the time spent by employees on eligible research and development activities and research and development costs incurred to external service providers. The research and development tax refund receivable is recognized as the company believes that it probable that the amount will be recovered in full through a future claim. A total of \$1.85 million is recognized as R&D tax refund income within government support income in the consolidated statements of operations and other comprehensive loss for fiscal year ended June 30, 2021 (\$1.03 million is receivable as at June 30, 2021 in the consolidated balance sheet).

Foreign currency translation

Assets and liabilities of foreign subsidiaries are translated from local (functional) currency to reporting currency (U.S. dollar) at the rate of exchange in effect on the consolidated balance sheets date; income and expenses are translated at the average rate of exchange prevailing during the year. The functional currency of GBS Inc. is the United States dollar. Foreign currency movements resulted in a loss of \$297,309 and \$147,081 for the years ended June 30, 2021 and 2020, respectively.

Income taxes

In accordance with the provisions of Financial Accounting Standards Board Accounting Standards Codification (FASB ASC) 740, *Income Taxes*, tax positions initially need to be recognized in the consolidated financial statements when it is more likely than not that the positions will be sustained upon examination by taxing authorities. It also provides guidance for de-recognition, classification, interest and penalties, accounting in interim periods, disclosure, and transition.

As of June 30, 2021, the Company had no uncertain tax positions that qualified for either recognition or disclosure in the consolidated financial statements. Additionally, the Company had no interest and penalties related to income taxes.

The Company accounts for current and deferred income taxes and, when appropriate, deferred tax assets and liabilities are recorded with respect to temporary differences in the accounting treatment of items for financial reporting purposes and for income tax purposes. Where, based on the weight of all available evidence, it is more likely than not that some amount of the recorded deferred tax assets will not be realized, a valuation allowance is established for that amount that, in management's judgment, is sufficient to reduce the deferred tax asset to an amount that is more likely than not to be realized.

Debt issuance cost

Debt issuance costs are amortized using the effective interest rate method over the term of the loan and the amortization expense is recorded as part of interest expense of the consolidated statements of operations.

Research and development costs

During the year, the Company contributed a total of \$2,600,000 towards budgeted development and commercialization costs to be incurred by BiosensX (North America) Inc. in which the company has a 50% interest. This represents the Company's contribution towards such costs budgeted in the Form S-1 relating to the development and preparation for submission of the Saliva Glucose Biosensor connected with regulatory approval for the U.S market by the U.S Food & Drug Administration. This amount is recognized as a prepayment and is being amortized as the expenses are incurred. Under the terms of the R&D agreement with BiosensX North America Inc., dated 20 April 2021, in which LSB D also committed to fund \$2,600,000 as a direct 50% shareholder in BiosensX North America Inc., the Company would have the right to apply any differences in contributions between LSB D and the Company towards any amounts owing between the Company and LSB D, including the exercise price of the Option (\$5 million) as included in the Option Agreement dated 31 March 2021 with LSB D (see Notes 5 and 9).

Net loss per share attributable to common shareholders (“EPS”)

The Company calculates earnings per share attributable to common shareholders in accordance with ASC Topic 260, *Earning Per Share*. Basic net income (loss) per share attributable to common shareholders is calculated by dividing net income (loss) attributable to common shareholders by the weighted average number of common shares outstanding during the period. Diluted net income (loss) per common share is calculated by dividing net income (loss) attributable to common shareholders by weighted average common shares outstanding during the period plus potentially dilutive common shares, such as share warrants.

Potentially dilutive common shares shall be calculated in accordance with the treasury share method, which assumes that proceeds from the exercise of all warrants are used to repurchase common share at market value. The number of shares remaining after the proceeds are exhausted represents the potentially dilutive effect of the securities.

As the Company has incurred net losses in all periods, certain potentially dilutive securities, including convertible preferred stock, warrants to acquire common stock, and convertible notes payable have been excluded in the computation of diluted loss per share as the effects are antidilutive.

Recently issued but not yet effective accounting pronouncements

As the Company is an emerging growth company, it has elected to defer the adoption of new accounting pronouncements until they would apply to private companies.

In August 2020, the FASB issued ASU 2020-06, which simplifies the guidance on the issuer’s accounting for convertible debt instruments by removing the separation models for (1) convertible debt with a cash conversion feature and (2) convertible instruments with a beneficial conversion feature. As a result, entities will not separately present in equity an embedded conversion feature in such debt and will account for a convertible debt instrument wholly as debt, unless certain other conditions are met. The elimination of these models will reduce reported interest expense and increase reported net income for entities that have issued a convertible instrument that is within the scope of ASU 2020-06. Also, ASU 2020-06 requires the application of the if-converted method for calculating diluted earnings per share and treasury stock method will be no longer available. ASU 2020-06 is applicable for fiscal years beginning after December 15, 2021, with early adoption permitted no earlier than fiscal years beginning after December 15, 2020. The Company does not intend to early adopt and continues to evaluate the impact of the provisions of ASU 2020-06 on its consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02, Leases (“ASU 2016-02”). This update requires all leases with a term greater than 12 months to be recognized on the balance sheet through a right-of-use asset and a lease liability and the disclosure of key information pertaining to leasing arrangements. This new guidance is effective for fiscal years beginning after December 15, 2021, and interim period within fiscal years beginning after December 15, 2022 as amended by ASU 2020-05 with early adoption permitted. The Company has not early adopted the standard and continues to evaluate the impact.

In December 2019, the FASB issued ASU No. 2019-12, Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes (“ASU 2019-12”), which is intended to simplify various aspects of the accounting for income taxes. ASU 2019-12 removes certain exceptions to the general principles in Topic 740 and also clarifies and amends existing guidance to improve consistent application. This standard is effective for fiscal years and interim periods within those fiscal years, beginning after December 15, 2020. Early adoption is permitted. The Company has not early adopted the standard and continues to evaluate the impact.

Concentration of credit risk

The Company places its cash and cash equivalents, which may at times be in excess of the Australia Financial Claims Scheme or the United States’ Federal Deposit Insurance Corporation insurance limits, with high credit quality financial institutions and attempts to limit the amount of credit exposure with any one institution.

Related parties

The Company has related party transactions with its parent LSBG. See Notes 8 and 9.

Fair value of financial instruments

The carrying value of financial instruments classified as current assets and current liabilities approximate fair value due to their liquidity and short-term nature.

NOTE 4. LICENSING RIGHTS

During the first quarter of the year ended June 30, 2020, the Company had purchased the license right to expand its territorial coverage from Greater China to include the APAC region, from LSB D for an amount of \$976,308 in relation to the development and approval process for the Saliva Biosensor Technology. The Company recorded the license at the historical carrying value in the books of LSB D which was \$nil and recorded the amount paid as a deemed dividend. The Company has agreed to pay royalties of sales and milestones payments as defined.

On September 12, 2019, the Company entered into an amended and restated license agreement for Saliva Biosensor Technology. On June 23, 2020 the Company entered into a license agreement with LSB D for the worldwide rights to SARS-CoV – 2 application of the Saliva Glucose Biosensor.

In relation to these licenses, there is no set expiration date for the license. However, the exclusivity of the license granted under the license agreement runs until the expiration of the patent portfolio covered by the agreement which is currently until 2033. No royalties have been incurred through to June 30, 2021 (June 30, 2020: \$nil).

On March 31, 2021, GBS entered into an agreement with LSB D to provide GBS an option to acquire an exclusive license to use LSB D's intellectual property in the treatment or management of diabetes field in North America (the "Option Agreement"). The Option Agreement has a term of two years and the exercise price of \$5 million. The fee of \$0.5 million incurred for the option has been recognized as an expense and included within 'Development and regulatory approval expenses' in the consolidated statement of operations.

NOTE 5. OTHER CURRENT ASSETS

Other current assets consist of the following:

	June 30, 2021	June 30, 2020
Goods and services tax receivable	\$ 83,278	\$ 7,509
Prepayments	2,424,143	29,469
Other receivables	1,596	12,084
Total	<u>\$ 2,509,017</u>	<u>\$ 49,062</u>

As of the year ended June 30, 2021, the Company made \$2,600,000 in prepayments for research and development. Of the total prepayments, \$504,000 is recorded as a non-current asset based on the expected outflow of the budgeted research and development costs. Under the terms of the R&D agreement with BiosensX North America Inc., dated 20 April 2021, in which LSB D also committed to fund \$2,600,000 as a direct 50% shareholder in BiosensX North America Inc., the Company would have the right to apply any differences in contributions between LSB D and the Company towards any amounts owing between the Company and LSB D, including the exercise price of the Option (\$5 million) as included in the Option Agreement dated 31 March 2021 with LSB D (see Notes 3 and 9).

NOTE 6. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses consist of the following:

	June 30, 2021	June 30, 2020
Accounts and other payables	\$ 1,355,894	\$ 483,576
Accruals	112,073	56,894
Related party payables	13,323	1,769,293
Employee liabilities (current and non-current)	124,246	246,999
Total	<u>\$ 1,605,536</u>	<u>\$ 2,556,762</u>

NOTE 7. CONVERTIBLE NOTES PAYABLE

The Company's previously outstanding notes mandatorily converted, at a conversion price equal to 85% of 50% of the unit offering price of the IPO (or \$7.23), for an aggregate of 710,548 shares based on \$5,133,706 of principal and zero accrued interest outstanding at the date of conversion.

The convertible notes had a contingent Beneficial Conversion Features ("BCF"), with the contingency being the event of IPO. As such, a financing cost of \$905,948 was recognized as interest expense in the consolidated statements of operations and other comprehensive loss in relation to this contingent BCF during the year ended June 30, 2021.

NOTE 8. SHAREHOLDERS' EQUITY

On December 14, 2020, the Company agreed to issue to LSB D, in consideration of LSB D's contribution towards the research and development of applications other than glucose and COVID-19 applications to a maximum of \$2 million over a 5-year period, a 5-year non-transferable warrant to purchase 3,000,000 shares of the Company's common stock at the exercise price of \$17.00 per share. As this was a transaction between entities under common control, the \$2 million receivable due from LSB D has been recognized as contra-equity.

On December 18, 2020, the Company entered into an Exchange Agreement (the "EA") with LSB D to exchange 3,000,000 shares of its common stock held by LSB D for 3,000,000 shares of the Company's Series B Convertible Preferred Stock ("Exchange"). In addition, the parties to the Exchange Agreement entered into a Registration Rights Agreement (the "RRA") pursuant to which the Company agreed to prepare and file within 30 days following the closing of the IPO with the Securities and Exchange Commission a registration statement to register for resale the shares of Common Stock issuable upon conversion of the Series B Convertible Preferred Stock. If and to the extent the Company fails to, among other things, file such resale registration statement or have it declared effective as required under the terms of the RRA, the Company will be required to pay to the holder of such registration rights partial liquidated damages payable in cash in the amount equal to the product of 1.0% multiplied by the aggregate purchase price paid by such holder pursuant to the EA. The EA and the RRA contain customary representations, warranties, agreements and, indemnification rights and obligations of the parties. The common stock acquired in the Exchange was immediately retired. Each share of Series B Convertible Preferred Stock is convertible into 1 share of the Company's common stock, subject to proportional adjustment and beneficial ownership limitations. In the event of the Company's liquidation, dissolution or winding up, holders of Series B Convertible Preferred Stock will participate *pari passu* with any distribution of proceeds to holders of the Company's common stock. Holders of Series B Convertible Preferred Stock are entitled to receive dividends on shares of Series B Preferred equal (on an as converted to common stock basis) to and in the same form as dividends actually paid on the Company's common stock. Shares of Series B Convertible Preferred Stock generally have no voting rights, except as required by law.

Initial public offering

In December 2020, the Company completed its initial public offering. See Note 1.

Post initial public offering

Since completion of the initial public offering in December 2020, Series A and Series B warrants held by certain shareholders were exercised. Each warrant is convertible into 1 share of the Company's common stock. A total of 59,800 Series A warrants and 1,400,995 Series B warrants were exercised and converted into common stock as of June 30, 2021.

A total of 1,700,000 Series B Convertible Preferred Stock was also converted into common stock as of June 30, 2021. Each share of Series B Convertible Preferred Stock is convertible into 1 share of the Company's common stock.

NOTE 9. RELATED PARTY TRANSACTIONS

The Company completed certain financing transactions with, LSB D as described in Note 8.

Sales to and purchases from related parties are made in arm's length transactions both at normal market prices and on normal commercial terms. The following transactions occurred with LSB D during the period July 1, 2020 to June 30, 2021 (FY2020: July 1, 2019 to June 30, 2020):

The Company incurred a total of \$523,767 (FY2020: \$588,206) towards the services in connection with development and regulatory approval pathway for the technology, including payments made or expenses incurred on behalf of the Company. The current year includes a fee of \$500,000 that was paid to acquire an option and has been recognized as an expense within development and regulatory approval expenses. On March 31, 2021, GBS entered into an Option Agreement with LSB D to provide GBS the option to acquire an exclusive license for LSB D's intellectual property. For further details, refer to Note 4.

The Company incurred a total of \$212,032 (FY2020: \$444,374) towards overhead cost reimbursement which includes salaries, rents and other related overheads directly attributable to the Company which are included in general and administration expenses.

The Company recognized income of \$nil (FY2020: \$118,923) in relation to shared labor reimbursement which includes salaries directly attributable to the Company which are included in Shared services revenue in the Consolidated Statements of Operations and Other Comprehensive Loss.

During the year ended June 30, 2021, the Company contributed a total of \$2,600,000 towards budgeted development and commercialization costs to be incurred by BiosensX (North America) Inc. relating to the development and preparation for submission of the Saliva Glucose Biosensor connected with regulatory approval for the U.S. market by the U.S. Food & Drug Administration. For further details, refer to Notes 3 and 5.

During the first quarter of the year ended June 30, 2020, the Company purchased the license right procurement assets from LSB D for an amount of \$976,308 in relation to the development and approval process for the Glucose Biosensor Technology. In accordance with FASB ASC 805, this was set to a zero book value, which equals the historical carrying value in the books of LSB D, by use of a deemed dividend (For further details, refer to Note 4). As of June 30, 2021, \$13,323 (June 30, 2020: \$1,769,293) remains payable to LSB D in relation to overhead reimbursements detailed above.

NOTE 10. INVESTMENT IN AFFILIATE

On May 29, 2020, LSB D, issued 14,000,000 common shares of BiosensX (North America) Inc. to the Company at par value of \$0.001 per share. This transaction provided the Company with a 50% interest in BiosensX (North America) Inc., the holder of the technology license for the North America region.

The investment in BiosensX (North America) Inc. is accounted for by use of the equity method in accordance with ASC 323 *Investments - Equity Method and Joint Ventures*.

At the date of this transaction, LSB D was the parent of both the Company and BiosensX (North America) Inc., the transfer of BiosensX shares to the Company was deemed to be a common control transaction. As a result of the share transfer, the Company has significant influence over BiosensX (North America) Inc. but, in accordance with ASC 810 *Consolidation*, LSB D is deemed to have control over BiosensX (North America) Inc. due to its direct ownership of 50% in BiosensX (North America) Inc. and indirect ownership of 50% in BiosensX (North America) Inc. through GBS Inc.

As of June 30, 2021, LSB D holds 42.6% of common Stock of GBS Inc. and therefore still has control over BiosensX (North America) Inc.

The following table summarizes the amount recorded in the consolidated financial statements:

	June 30, 2021	June 30, 2020
Investment value	\$ 135,692	\$ 14,000
(Loss) income from the affiliate	(135,692)	121,692
Carrying amount	\$ —	\$ 135,692

NOTE 11. COMMITMENTS AND CONTINGENCIES

On January 21, 2021, the Company entered into a sponsored research agreement with Johns Hopkins Bloomberg School of Public Health to accelerate the development of next-generation saliva-based diagnostic tests. The Company is collaborating with the Bloomberg School of Public Health to optimize the collection of saliva and monitoring of diverse biomarkers across a number of modalities including clinical chemistry and infectious diseases. Johns Hopkins intend to utilize biosensor products to conduct in-field epidemiological studies. The Company agreed to pay Johns Hopkins a total amount of \$423,589 as a part of this sponsored research agreement of which \$211,795 remains payable as of June 30, 2021.

On January 5, 2021, the Company entered into a certain Research Collaboration Agreement with Harvard College for the purposes of facilitating mutual collaboration in scientific research in connection with the Company's non-exclusive royalty free license to combat COVID-19 coronavirus. The contemplated collaboration includes research teams from the Company and Harvard and will include, among others, exchange of materials and research data, to now progress with the milestone of integrating the Harvard technology with the Company's biosensor with applications for SARS-Cov-2 antibody test for COVID-19. The Company agreed to pay Harvard a total amount of \$609,375 payable in 3 instalments of which \$152,344 remains payable as of June 30, 2021.

The Company has no material future minimum lease commitments or purchase commitments those discussed above.

From time to time, the Company may become a party to various legal proceedings arising in the ordinary course of business. Based on information currently available, the Company is not involved in any pending or threatened legal proceedings that it believes could reasonably be expected to have a material adverse effect on its financial condition, results of operations or liquidity. However, legal matters are inherently uncertain, and the Company cannot guarantee that the outcome of any potential legal matter will be favorable to the Company.

NOTE 12. INCOME TAX

We compute income taxes using the asset and liability method in accordance with FASB ASC Topic 740, *Income Taxes*. Under the asset and liability method, we determine deferred income tax assets and liabilities based on the differences between the financial reporting and tax bases of assets and liabilities and measure them using currently enacted tax rates and laws. We provide a valuation allowance for deferred tax assets that, based on available evidence, are more likely than not to be realized. Realization of our net operating loss carryforward was not reasonably assured as of June 30, 2021 and 2020, and we have recorded a valuation allowance of \$5,946,731 and \$4,175,349, respectively, against deferred tax assets in excess of deferred tax liabilities.

The components of net deferred taxes are as follows:

	As of June 30,	
	2021	2020
Deferred tax assets (liabilities):		
Net operating loss – U.S.	\$ 4,572,130	\$ 3,508,533
Net operating loss - Foreign	1,486,444	676,471
Employee Benefits	26,091	5,322
R&D Credit	(215,346)	-
Foreign Exchange	77,412	(14,977)
Total deferred tax assets, net	5,946,731	4,175,349
Less: valuation allowance	(5,946,731)	(4,175,349)
Net deferred taxes	\$ -	-

Our statutory income tax rate is expected to be approximately 21%. The provision for income taxes consisted of the following:

	Years Ended June 30	
	2021	2020
Current	\$ -	\$ -
Deferred	-	-
Total	\$ -	\$ -

The reconciliation between the income tax expense (benefit) calculated by applying statutory rates to net loss and the income tax expense reported in the accompanying consolidated financial statements is as follows:

	Years Ended June 30,	
	2021	2020
U.S. federal statutory rate applied to pretax income (loss)	\$ (1,540,265)	\$ 691,655
State taxes, net of federal benefit	-	-
Permanent differences	-	-
Benefit of federal operating loss carryforwards	-	-
Cumulative adjustment to deferred taxes	(231,117)	(9,656)
Change in state tax rates and other	-	-
Change in valuation allowance	\$ (1,771,382)	\$ 681,999
	\$ -	\$ -

As of June 30, 2021, and 2020, we had federal and foreign income tax net operating loss carryforwards of approximately \$28,317,769 and \$19,882,612, respectively, which expire at various dates ranging from 2038 through unlimited expiration.

NOTE 13. LOSS PER SHARE

Basic loss per common share is computed by dividing net loss allocable to common shareholders by the weighted average number of shares of common stock or common stock equivalents outstanding. Diluted loss per common share is computed similar to basic loss per common share except that it reflects the potential dilution that could occur if dilutive securities or other obligations to issue common stock were exercised or converted into common stock.

	Year Ended June 30,	
	2021	2020
Net loss attributable to GBS, Inc.	\$ (7,037,286)	\$ (3,163,776)
Basic and diluted net loss per share attributed to common shareholders	\$ (0.68)	\$ (0.37)
Weighted-average number of shares outstanding	10,414,886	8,510,329

The following outstanding warrants, options and preferred shares were excluded from the computation of diluted net loss per share for the periods presented because their effect would have been anti-dilutive:

	Year Ended June 30,	
	2021	2020
Warrants - Series A	1,401,377	-
Warrants - Series B	60,182	-
Warrants issued to underwriters	63,529	-
Pre IPO warrants	2,736,675	2,250,376
Warrants issued to parent entity	3,000,000	-
Preferred stock - Series A	-	2,323,891
Preferred stock - Series B	1,300,000	-

NOTE 14. SUBSEQUENT EVENTS

On July 15 20021, the Company signed an agreement with L.E.K. Consulting Hong Kong Pty Limited (“L.E.K. Consulting”) for \$ 300,000 to identify and recommend a short list of suitable commercial partners or sub-licensees for distribution in APAC region.

Subsequent to June 30, 2021, and through to the date of this filing, the remaining outstanding Series B Convertible Preference Stock was converted into common stock.

Subsequent to June 30, 2021 and through to the date of this filing, a total of 400 Series B Warrants were exercised to purchase one Common Stock in a cashless exercise.

**DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE
ACT OF 1934**

GBS Inc. (the "**Company**" "**we**" or "**our**") has one class of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended, the Company's common stock, par value \$0.001 per share (the "**Common Stock**"). The Common Stock is currently listed on The NASDAQ Global Market under the symbol "GBS".

The following summary of the terms and provisions of the Common Stock does not purport to be complete and is qualified in its entirety by reference to the pertinent sections of our Amended and Restated Certificate of Incorporation, our Amended and Restated By-laws and to the applicable provisions of Delaware law.

Authorized Capital Stock

Our Amended and Restated Certificate of Incorporation authorizes us to issue 100,000,000 shares of Common Stock, par value \$0.01 per share; and 10,000,000 shares of preferred stock, par value \$0.01 per share.

Common Stock

The holders of our Common Stock are entitled to one vote for each share held of record on all matters submitted to a vote of the stockholders, including the election of directors, and do not have cumulative voting rights. Accordingly, the holders of a majority of the outstanding shares of Common Stock entitled to vote in any election of directors can elect all of the directors standing for election, if they so choose, other than any directors that holders of any preferred stock we may issue may be entitled to elect.

Subject to limitations under Delaware law and preferences that may be applicable to any then outstanding preferred stock, holders of Common Stock are entitled to receive ratably those dividends, if any, as may be declared by our Board of Directors out of legally available funds.

In the event of any voluntary or involuntary liquidation, dissolution or winding up of our affairs, the holders of our Common Stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of or provision for all of our debts and other liabilities, subject to the prior rights of any Preferred Stock then outstanding.

Holders of Common Stock have no preemptive or conversion rights or other subscription rights and there are no redemption or sinking funds provisions applicable to the Common Stock.

Preferred Stock

Our Board of Directors currently has the authority, without further action by our stockholders, to issue shares of preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting, or the designation of, such series, any or all of which may be greater than the rights of Common Stock. The issuance of preferred stock could adversely affect the voting power of holders of Common Stock and the likelihood that such holders will receive dividend payments and payments upon our liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing a change in control of our company or other corporate action.

Series B Convertible Preferred Stock

Each share of our Series B Convertible Preferred Stock (the “**Series B Preferred Stock**”) is convertible at any time at the holder’s option into one share of Common Stock (subject to the beneficial ownership limitations as provided in the Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock (the “**Certificate of Designation**”)), subject to adjustment as provided in the Certificate of Designation, provided that the holder will be prohibited from converting Preferred Stock into shares of our Common Stock if, as a result of such conversion, the holder, together with its affiliates, would own more than 4.99% (or, at the election of the purchaser prior to the date of issuance, 9.99%) of the total number of shares of our Common Stock then issued and outstanding. However, any holder may increase or decrease such percentage to any other percentage not in excess of 9.99%, provided that any increase in such percentage shall not be effective until the 61st day after such notice to us. The Certificate of Designation designates 3,000,000 shares as Preferred Stock.

In the event of our liquidation, dissolution, or winding up, holders of our Preferred Stock will be entitled to receive the amount of cash, securities or other property to which such holder would be entitled to receive with respect to such shares of Preferred Stock if such shares had been converted to Common Stock immediately prior to such event (without giving effect for such purposes to the 4.99% or 9.99% beneficial ownership limitation, as applicable) subject to the preferential rights of holders of any class or series of our capital stock specifically ranking by its terms senior to the Preferred Stock as to distributions of assets upon such event, whether voluntarily or involuntarily.

Shares of Preferred Stock are not entitled to receive any dividends, unless and until specifically declared by our board of directors. However, holders of our Preferred Stock are entitled to receive dividends on shares of Preferred Stock equal (on an as-if-converted-to-common-stock basis) to and in the same form as dividends actually paid on shares of the Common Stock when such dividends are specifically declared by our board of directors, except for stock dividends or distributions payable in shares of Common Stock on shares of Common Stock or any other Common Stock equivalents for which the conversion price will be adjusted. We are not obligated to redeem or repurchase any shares of Preferred Stock. Shares of Preferred Stock are not otherwise entitled to any redemption rights, or mandatory sinking fund or analogous fund provisions.

The holders of the Preferred Stock have no voting rights, except as required by law. We may not disproportionately alter or change adversely the powers, preferences and rights of the Preferred Stock or amend the Certificate of Designation or amend our Amended and Restated Certificate of Incorporation or our Amended and Restated By-laws in any manner that disproportionately adversely affect any right of the holders of the Preferred Stock without the affirmative vote of the holders of a majority of the shares of Preferred Stock then outstanding.

Anti-Takeover Effects of Provisions of Our Certificate of Incorporation, Our By-laws and Delaware Law

Some provisions of Delaware law, our Amended and Restated Certificate of Incorporation and our Amended and Restated By-laws contain provisions that could make hostile takeovers, including the following transactions, more difficult: an acquisition of us by means of a tender offer; an acquisition of us by means of a proxy contest or otherwise; or the removal of our incumbent officers and directors. As a consequence, they may also inhibit temporary fluctuations in the market price of our Common Stock that often result from actual or rumored hostile takeover attempts. These provisions may also have the effect of preventing changes in the composition of our board and management. It is possible that these provisions could make it more difficult to accomplish or could deter transactions that stockholders may otherwise consider to be in their best interest or in our best interests, including transactions which provide for payment of a premium over the market price for our shares.

These provisions, summarized below, are intended to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our Board of Directors. We believe that the benefits of the increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us outweigh the disadvantages of discouraging these proposals because negotiation of these proposals could result in an improvement of their terms.

We are subject to Section 203 of the Delaware General Corporation Law, which prohibits persons deemed to be “interested stockholders” from engaging in a “business combination” with a publicly held Delaware corporation for three years following the date these persons become interested stockholders unless the business combination is, or the transaction in which the person became an interested stockholder was, approved in a prescribed manner or another prescribed exception applies. Generally, an “interested stockholder” is a person who, together with affiliates and associates, owns, or within three years prior to the determination of interested stockholder status did own, 15% or more of a corporation’s voting stock. Generally, a “business combination” includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. The existence of this provision may have an anti-takeover effect with respect to transactions not approved in advance by the Board of Directors. A Delaware corporation may “opt out” of these provisions with an express provision in its original certificate of incorporation or an express provision in its certificate of incorporation or by-laws resulting from a stockholders’ amendment approved by at least a majority of the outstanding voting shares. We have not opted out of these provisions. As a result, mergers or other takeover or change in control attempts of us may be discouraged or prevented.

Transfer Agent and Registrar

The transfer agent for our Common Stock is Continental Stock Transfer & Trust Company, 17 Battery Place, New York, New York 10004.

List of Subsidiaries of Registrant

Name	Jurisdiction of Incorporation or Organization
Glucose Biosensor Systems (APAC) Pty Ltd	New South Wales, Australia
GBS Operations Inc.	Delaware

OFFICER'S CERTIFICATION PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Harry Simeonidis, certify that:

1. I have reviewed this Annual Report on Form 10-K of GBS, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

September 15, 2021

/s/ Harry Simeonidis

Harry Simeonidis, Chief Executive Officer
(Principal Executive Officer)

OFFICER'S CERTIFICATION PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Spiro Sakiris, certify that:

1. I have reviewed this Annual Report on Form 10-K of GBS, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

September 15, 2021

/s/ Spiro Sakiris

Spiro Sakiris, Chief Financial Officer
(Principal Financial and Accounting Officer)

CERTIFICATION PURSUANT TO

18 U.S.C. SECTION 1350,

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K for the year ended June 30, 2021 of GBS, Inc. (the "Company") as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Harry Simeonidis, the Chief Executive Officer of the Company, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C 78m or 78o(d));and
- The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

September 15, 2021

/s/ Harry Simeonidis

Harry Simeonidis

Chief Executive Officer

(Principal Executive Officer)

A signed original of this written statement required by Section 906 has been provided to GBS, Inc. and will be retained by GBS, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

CERTIFICATION PURSUANT TO

18 U.S.C. SECTION 1350,

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K for the year ended June 30, 2021 of GBS, Inc. (the "Company") as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Spiro Sakiris, the Chief Financial Officer of the Company, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C 78m or 78o(d));and
- The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: September 15, 2021

/s/ Spiro Sakiris

Spiro Sakiris

Chief Financial Officer

(Principal Financial and Accounting Officer)

A signed original of this written statement required by Section 906 has been provided to GBS, Inc. and will be retained by GBS, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.
