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John D. Vandermosten, CFA
312-265-9588 / jvandermosten@zacks.com

scr.zacks.com
10 S. Riverside Plaza, Suite 1600, Chicago, IL 60606

GBS, Inc. (GBS - NASDAQ)

Spit it Out: Testing Without the Blood

Based on our DCF model and a 15% discount rate, GBS is valued at approximately $5.00 per share. Our model applies a 90% probability of ultimate approval and commercialization of the Saliva Glucose Biosensor and COVID antibody test. The model includes contributions from North America, Asia Pacific and other developed markets.

Current Price (12/31/2021)	$1.44
Valuation	**$5.00**

INITIATION

GBS is developing saliva-based, non-invasive biosensors for use in glucose monitoring in diabetes and antibody detection in COVID-19. Advances in organic thin-film transistors have paved the way to inexpensive, easy to manufacture, flexible and sensitive devices. If successful, the technology could impact the lives of millions of diabetics who have relied on finger-prick standard-of-care, which can be painful, cumbersome and inconvenient, elements which can interfere with management of the condition.

In preclinical work, GBS' saliva glucose biosensor production in artificial saliva in in progress to meet the ISO standard for glucose monitoring accuracy and consistency. GBS now needs to coordinate with regulatory authorities in the Asia Pacific and North America regions. GBS is now conducting collection protocol and correlation studies in preparation for pivotal studies. The FDA has provided guidance suggesting the *De Novo* application pathway for the saliva glucose biosensor.

GBS' biosensing technology can also be applied to detection of SARS-CoV-2 infection, and GBS has partnered with Harvard's Wyss Institute for a combination approach leveraging Wyss' eRapid technology to detect COVID-19 infection.

SUMMARY DATA

52-Week High	**9.63**
52-Week Low	**1.26**
One-Year Return (%)	**-80.5**
Beta	**N/A**
Average Daily Volume (sh)	**870,622**
Shares Outstanding (mil)	**14.9**
Market Capitalization ($mil)	**21.4**
Short Interest Ratio (days)	**0.15**
Institutional Ownership (%)	**2.31**
Insider Ownership (%)	**20.1**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2022 Estimate	**N/A**
P/E using 2023 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Above Average**
Type of Stock	**Small-Growth**
Industry	**Med-Instruments**

ZACKS ESTIMATES

Revenue

(In millions of USD)

	Q1 (Sep)	Q2 (Dec)	Q3 (Mar)	Q4 (Jun)	Year (Jun)
2021	$0.0 A	$0.3 A	$0.0 A	$1.6 A	$2.0 A
2022	$0.0 A	$0.0 E	$0.0 E	$0.0 E	$0.0 E
2023					$1.9 E
2024					$17.5 E

Earnings per Share

	Q1	Q2	Q3	Q4	Year
2021	-$0.12 A	-$0.23 A	-$0.27 A	-$0.07 A	-$0.68 A
2022	-$0.10 A	-$0.16 E	-$0.16 E	-$0.18 E	-$0.60 E
2023					-$0.26 E
2024					-$0.16 E

INITIATION

The number of diagnostic tests used to evaluate biological material has exploded over the last decades. These tests help identify disease, determine treatment and show whether or not a condition is under control among other benefits. One of the earliest conditions evaluated using diagnostic tests was diabetes. The first recorded tests were conducted on urine, but later evolved into more precise methods using blood and interstitial fluid. As technology moved ahead in diabetes detection, tests using acid hydrolysis were streamlined to test strips that could check blood for sugar. In the present day, a finger stick blood sugar test is the most common way for people with diabetes to monitor their blood sugar. Accurate blood sugar readings are important for guiding diet, medication administration, exercise routines and other behavior in order to avoid long term health complications such as blindness, amputation and nerve damage.

While blood tests provide point of care readouts and are a dramatic improvement over prior approaches, there are downsides. The test requires draw site cleaning and preparation, a painful prick to the skin which can lead to numbness and scarring over time and risk of soreness, swelling and bruising. Accuracy can be affected by atmospheric conditions, location of prick and the quality of test strips. With younger diabetics, the pain and fear of needles may make sample collection difficult. With the advent of organic thin-film transistor (OTFT) technology, greater levels of sensitivity now allow for non-invasive alternatives for sampling to be used for quantifying blood sugar. The cost of printed OTFT sensors is competitive with blood test strips and saliva samples address many of the challenges associated with blood testing.

Saliva testing can be used in a broad range of diseases and conditions. It is non-invasive and can be collected by the patient, reducing the need for and risk to healthcare professionals. Using new, highly sensitive techniques, even minute levels of analyte in saliva can be measured. In the case of GBS' technology, the cost of an OTFT strip is less than a cent, providing an economic incentive for a saliva test. While GBS has not yet clinically demonstrated the accuracy of its biosensor platform, there are multiple precedents for using saliva for COVID testing and current work for the glucose test is in a process to correlate and calibrate readings between plasma and saliva glucose.

The utility of saliva testing is broader than diabetes and may be used to detect cancer biomarkers, conduct immunological tests, identify hormones, determine viral infection, test for HIV and monitor systematic drug levels. A cancer diagnostic can observe mutated extra-cellular DNA and RNA, while a hormone detection kit can identify the levels of cortisol, estrogen, progesterone and androgen hormones. These examples are only the tip of the iceberg for this emerging platform technology.

GBS was presented as an initial public offering (IPO) and spun out of Life Science Biosensor Diagnostics (LSBD) in December 2020. The company holds rights to develop and commercialize saliva-based tests and will initially target the glucose and COVID test markets. GBS holds rights to develop and commercialize saliva glucose biosensor tests in the Asia Pacific region and an antibody COVID test globally. As of September 30, 2021, GBS is approximately 30% owned by LSBD and itself owns 50% of BioSensX, a joint venture between GBS and LSBD to commercialize the saliva glucose biosensor in North America.

GBS is in the development stage for both the glucose and COVID biosensor. The glucose test is now undergoing work to define the relationship between saliva and plasma glucose, to develop an algorithm between saliva and glucose, and to validate the algorithm and generate prospective data for full regulatory approval with the FDA. This work is expected to be complete in 2022 leading to a pivotal study that should generate registrational data by 2023. A clinical validation study was conducted for the COVID test and preliminary findings were recently shared. Analysis from the validation study provides support for the start to the COVID salivary antibody test trials which may include Emergency Use Authorization (EUA). The COV2T test will target three primary markets: post-vaccination screening, diagnosis, and informing the decision to discharge recovered patients.

Many diagnostic tests require a blood draw and expensive lab equipment to generate the required results. Not only does a blood draw have its downsides, but regularly submitting a sample to the lab is a time consuming and costly process that prevents effective monitoring and response to certain diseases. Examples where use could be particularly beneficial include monitoring hyperlipidemia or anemia, evaluating performance of drugs during titration or in a clinical setting, or when constant surveillance is necessary for drug performance.

As GBS progresses, we look forward to correlation and algorithm results from the glucose studies, further detail on the SARS-CoV-2 biosensor, and additional information regarding commercialization partners. Success in these areas will guide the future direction of our price target.

Key reasons to own GBS shares:

- **Organic thin-film transistor biosensor**
  - **Low cost**
  - **Easily produced**
  - **Accurate and sensitive**
- **Large addressable testing markets**
  - **Diabetes**
  - **COVID-19**
  - **Oncology Diagnostics & Staging**
  - **Luteinizing Hormone**
  - **Nucleic Acids**
- **Attractive research collaborations**
  - **Harvard's Wyss Institute**
  - **Johns Hopkins Bloomberg**
- **Commercialization rights to Asia-Pacific region including China**
- **Option to purchase rights to North American region**
- ***De Novo* application pathway**

In this report we will provide a review of saliva testing and the biosensor technology used to identify analytes in this medium. Included is a section discussing the OTFT technology and it commercial viability. GBS' technology is examined, including its anticipated manufacturing process of reel to reel printing. The report delves into the opportunity for antibody detection and identifies other clinical indications that GBS is pursuing. The following section discusses GBS' primary indications in diabetes and COVID-19, examining the prevalence, contributing factors, risks and treatment of the conditions. We also review existing diagnostic testing approaches for each.

An examination of the company's intellectual property is followed by an exposition on the competitive environment, licensing details and collaborations. A review of recent financial and operational results is followed by management profiles and the broad and specific risks faced by GBS. After summarizing the competitive environment, we conclude with our valuation assumptions and target price. The result of our work generates a value of $5.00 per share.

Technology and Products

Saliva Testing

Many bodily fluids are used for diagnostic testing. They range from the easy to collect (urine for example) to the difficult (cerebrospinal fluid [CSF]). According to LabCorp, one of the leading laboratory testing companies in the United States, bodily fluids that are regularly tested include blood, urine, semen, sweat, amniotic fluid, CSF, synovial and peritoneal among others. While it has not historically been one of the leading approaches, saliva testing is becoming more common for diagnostic testing. Saliva presents many advantages compared with other biological fluids as it is easily collected and stored, does not require specialized equipment to accumulate and can be gathered by the individual providing the sample. With advances in detection technology, new approaches with higher sensitivity have made it possible to use saliva to detect a broad spectrum of analytes.

Exhibit I – Analytes Detected in Saliva[1]

Analyte	Examples
Hormones	Cortisol, androgens, testosterone, estriol, estrogen
Steroids	Cortisone, progesterone, aldosterone, DHEAS
Antibodies	IgG, IgA, sIgA, IgM
Growth Factors	EGF, NGF, VEGF, IGF
Cytokines and Chemokines	IL-1 beta, IL-8, IL-6, MCP-1, CX3CL1, GRO-1 alpha, troponin I, TNF alpha
Nucleic Acids	DNA, mRNA, siRNA, micro RNA
Proteins	Many, up to the 1000s
Drugs	NIDA 5, ethanol, therapeutic drugs, anticonvulsants, antipyretic/analgesics, antineoplastic agents, antibacterial agents, bronchodilators, cotinine

Saliva is a fluid secreted by salivary glands in the mouth which contains enzymes, hormones, antibodies and antimicrobial constituents among other components. The fluid aids in digestion, limits growth of pathogens, protects teeth from decay, lubricates the mouth and helps in swallowing. Blood and saliva share many of the same compounds as they exchange them through a number of mechanisms. The presence of many disease-signaling biomarkers in saliva make it a useful diagnostic analyte.

Collection
Saliva collection is much easier and safer compared with other fluid-based analytes. Collection is simple and noninvasive and can be performed by the individual giving the sample. It is painless and an attractive alternative to collecting blood, especially for hemophiliacs, young children, the elderly and disabled.

Biosensors

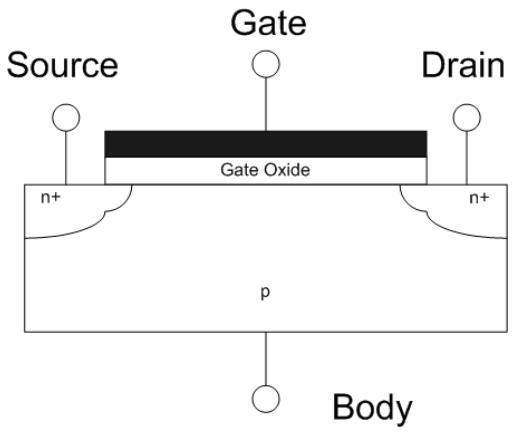
Biosensors are small, self-contained devices used to detect and analyze biological substances. The sensors are able to recognize analytes as well as generate, recognize, produce, transduce and interpret signals. Four types of biosensors dominate which are categorized by the type of transducer: electrochemical, optical, thermal and piezoelectric. The biosensor, through interaction with the analyte, measures and quantifies the analyte and sends an amplified signal to the display for interpretation. In contrast to earlier biosensors, the current generation includes the bioreceptor molecule as part of the base sensing platform. GBS' sensing is of the electrochemical variety.

At the heart of GBS' saliva glucose biosensor is printable OTFT technology. Compared with inorganic counterparts, organic semiconductors are far less expensive and easier to produce, especially when coupled with reel-to-reel printing technology. The hurdle for OTFT's success was to achieve sensitivity comparable with silicon transistors. The ability to efficiently and inexpensively mass produce a noninvasive sensor that is accurate enough for repeated measurements of very small amounts of analyte in saliva is a significant feat, and one that has the potential to im-

[1] Compiled by Zacks' analysts with data provided in Malamud, Daniel; Rodriguez-Chavez, Isaac. Saliva as a Diagnostic Fluid. Dent Clin North Am. 2011 Jan; 55(1): 159–178. doi: 10.1016/j.cden.2010.08.004

prove the lives of millions of diabetics. The key innovation of the Saliva Glucose Biosensor (SGB) is the sensitivity that enables it to linearly detect glucose in saliva at concentrations between 8-200 µM, a level 1/100th of that for blood.

Exhibit II - Example Transistor[2]



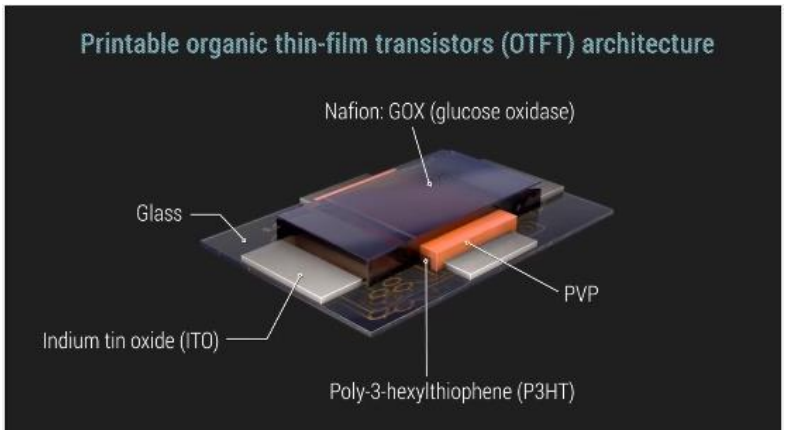
In general, transistors leverage the properties of semiconductors to act as electron gates or valves. Typically, they comprise a source, gate and drain, also known as an emitter, base and collector, respectively. Together they allow the flow of electrons across the transistor, controlled by the gate/base. Because a semiconductor has varying conductivity with small charges applied to the gate, it can act as an amplifier for small signals. A biosensor is fundamentally an amplifier of weak signals, typically related to charged biological molecules. The charged species can interact with the gate/base of the transistor, affect the charge on the gate, which in turn alters the flow of electrons through the transistor. The current through the transistor can be analyzed as a proxy for the presence of charged species on or near the gate. However, the smaller the molecule, the smaller its charge and the more difficult it is to detect accurately, requiring high performance from the device. Biosensors can also be used to identify changes in pH or, in the case of GBS' candidate, hydrogen ions as a byproduct of glucose oxidase (GOx) metabolism of glucose.[3] The gate and drain voltage measure the decomposition of hydrogen peroxide into H_2O and H^+ (hydrogen ion) but insufficient energy levels exist for hydrolysis to occur. Nafion is used in the glucose sensor and provides the pathway for the protons (hydrogen ions) that are produced from the hydrogen peroxide (H_2O_2) to reach the transistor channel thereby boosting sensitivity.

OTFTs hold promise of minimal cost, as the materials are more accessible and available and can be fabricated at low temperatures using energy conserving techniques such as ink-jet printing. Furthermore, printing can be done on flexible substrates, such as a test strip. OTFTs are also preferred over silicon-based transistors as critical organic sensing molecules such as glucose oxidase are incompatible with silicon transistors.

Commercially viable organic transistors have been sought after for decades. Because silicon and carbon have similar valence structure, chemists theorized that carbon could potentially behave like silicon. Replacing or supporting silicon with carbon could generate potential cost savings. While organic transistors have held promise in terms of cost savings and ease of production among other benefits, the challenge was to achieve organic transistors that had performance comparable to their inorganic (silicon) counterparts. Like silicon-based transistors, OTFT structure comprises a source and drain electrode, a semiconducting layer, a gate electrode, and a dielectric layer; however, unlike silicon transistors, the organic layers can be coated or printed onto a substrate. In the case of GBS' biosensor, the transistor also features a layer of glucose oxidase enzymes that act on glucose in the saliva to aid in detection.

[2] Illustration by Fadeaway919, with permission granted to copy by GNU Free Documentation License.
[3] Glucose oxidase is an enzyme that catalyzes the conversion of beta-D-glucose and diatomic oxygen into D-glucono-1,5-lactone and hydrogen peroxide.

Exhibit III - Saliva Glucose Biosensor[4]



Thin film transistors (TFTs) are made up of thin films of semiconducting materials placed on a supporting substrate. Glass is normally used as the substrate, but other materials such as plastic and paper can be used. TFTs can be manufactured using a wide variety of materials including silicon, cadmium selenide, metal oxides, carbon nanotubes and even organic semiconductors. The TFTs are suitable for applications in disposable saliva glucose test strips. GBS' saliva glucose biosensor is printed on glass. The design of the glucose-sensing OTFT uses PVP, or poly[4-vinylphenol], as a gate dielectric, or a nonconductive layer that enables gate function, uses P3HT, or poly-3-hexylthiophene, as the organic semiconductor channel, GOx-conjugated Nafion for the gate, and indium tin oxide (ITO) as source and drain electrodes.

Reel to Reel Printing

GBS' biosensor is manufactured using modified reel-to-reel printing technology that was developed at the Australian National Fabrication Facility. This printing technology allows low-cost mass production. Previous research published in the journal *Solar Energy Materials and Solar Cells* showed that the cost to manufacture printed organic electronic devices can be as low as $7.85 per square meter. With the size of GBS' printed biosensor at approximately one square centimeter, this equates to about $0.001 per biosensor.

Exhibit IV - Reel-to-reel printer[5]

The Australian National Fabrication Facility is set up to produce the saliva glucose biosensors, and GBS has used the facility to produce multiple batches for testing. GBS management expects these facilities to be able to support very early production for commercialization on a cost-recovery basis.

Using saliva glucose concentration as an indicator for blood glucose is supported by extensive scientific literature, which has been published in independent journals such as the *Journal of Obesity, the Journal of International Oral*

[4] GBS Inc. - Real-time, point-of-care testing at the tip of your tongue
[5] GBS Inc. - Real-time, point-of-care testing at the tip of your tongue

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.

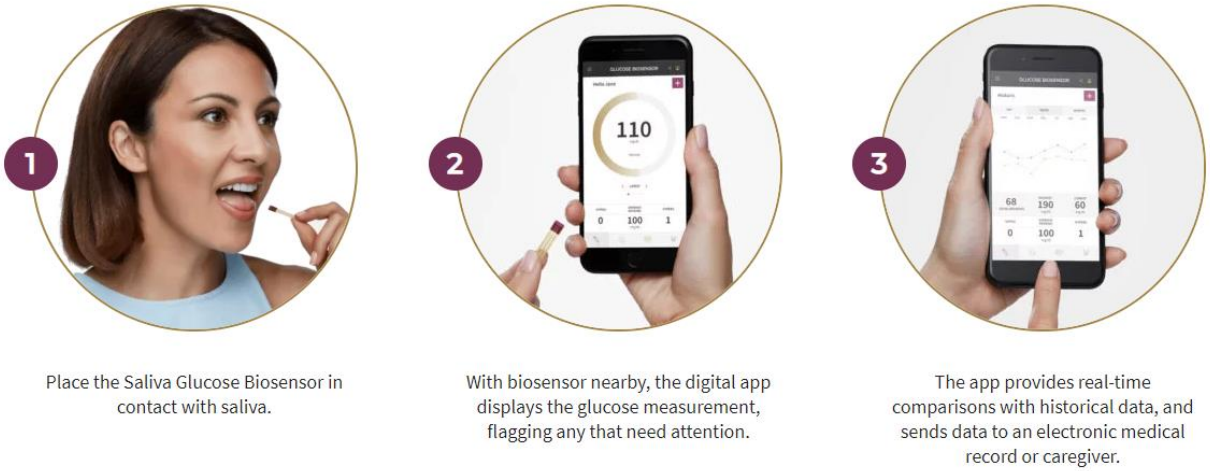
GBS' saliva glucose biosensor has been under continuous development for over six years, first by the University of Newcastle, Australia, then by Life Science Biosensor Diagnostics and subsequently by GBS. Currently, GBS' saliva test is in the clinical validation phase of development that precedes regulatory submission. The university research team used ISO standard 15197:2013 as a benchmark. This standard specifies that:

- 95% of results have to be within +/- 15 mg/dl when compared to a traceable laboratory method at glucose concentrations less than 100 mg/dl and within +/-15% at blood glucose concentrations above 100 mg/dl;
- In a consensus error grid at least 99% of results have to be within zones A and B.

To test the accuracy of the technology, artificial saliva was prepared based on the Fusayama Meyer solution, consisting of 11 different glucose concentrations from 0 to ~180 mg/dL. Concentrations from 0 to ~9 mg/dL were within a physiological expected range. Concentrations in excess of what was expected physiologically were used to test the limits of the biosensor's linearity. From the 116 devices assessed, 110 devices (94.8%) met the blood glucose ISO standard in relation to the adapted system accuracy. This was just shy of the 95% threshold required by the standard.

Beyond the sensor itself, GBS aims to create an app-based digital environment, driven by artificial intelligence (AI) that can collect data on the end user. This data can be used to help drive patient outcomes. To interface with the smart device, an intermediate device has been developed that bridges communication between the saliva biosensor strip and the smart device. Management has suggested eliminating this intermediate device altogether in favor of Near Field Communication (NFC), to enable communication between the strip and the smart device. Such NFC tags are readily and inexpensively produced.

Exhibit V - GBS SGB Three-step Process[6]



On February 18, 2021, GBS announced the execution of a sponsored research agreement with Johns Hopkins Bloomberg School of Public Health to accelerate development of next-generation saliva-based diagnostic tests. Together, the goal is to identify the best biomarkers in the salivary matrix to support both GBS' glucose sensing, diabetes program, as well as GBS' COVID-19 initiative.

COV2 Test (COV2T)

COV2T Point-of-Care Biosensor Diagnostic

The COVID-19 pandemic presented an immediate and significant challenge to global healthcare. Despite COVID's unexpected rise, many companies owned technologies that were directly applicable to addressing it. GBS' biosensor technology has the potential to produce a rapid, accurate and widely accessible saliva test to identify antibodies related to SARS-CoV-2 infection. In fact, a recent paper from Pisianic *et al.* at Johns Hopkins Department of Environmental Health and Engineering, Bloomberg School of Public Health featured results that supported the feasibility

[6] The Saliva Glucose Biosensor - GBS Inc.

of measurement of anti-SARS-CoV-2 IgG (antibodies) via the salivary matrix to identify individuals who were infected.[7] GBS sees potential in detecting not only antibodies, but genetic signatures (RNA) for COVID-19. Such a test could have strong implications for population-level monitoring infections as SARS-CoV-2 mutants emerge. Current tests (PCR)[8] require collecting the biological sample and sending it off to a laboratory for analysis, whereas GBS' approach, if successful, may be able to provide real-time, point-of-care results available in less than ten minutes.[9] Furthermore, a saliva test may be highly desirable when compared to deep nasal swabbing for both patient and provider.

As evidence that saliva is a viable medium for COVID-19 infection detection, Pisianic *et al.*[10] demonstrated results from saliva that was collected ≥10 days post symptom onset. The anti-SARS-CoV-2 IgG assay detected infection with 100% sensitivity and 99% specificity. In addition, it was demonstrated that the temporal kinetics of SARS CoV-2-specific IgG responses in saliva were consistent with serum kinetics, indicating that most individuals will be able to test positive approximately 10 days after COVID-19 symptoms emerge or approximately two weeks after infection.

GBS intends to use section 564 of the Federal Food, Drug, and Cosmetic (FD&C) Act to guide its application which provides the foundation for Emergency Use Authorization (EUA) of *in vitro* diagnostics for the detection and/or diagnosis of COVID-19. EUA requires less stringent evidence of efficacy, due to the urgency of the situation, and can utilize indirect evidence to lend support for approval. Therefore, GBS could potentially market COV2T in an expedited manner. As this is a time-sensitive initiative, GBS is placing the needed resources behind the program. If approved, COV2T could serve to assist in population screening, diagnosis, and post-vaccination screening in the battle against COVID-19.

Preclinical Indications

GBS' biosensor has the potential to be a platform technology. In addition to diabetes and COVID-19, GBS' OTFT biosensor has wide ranging applications. GBS has identified up to 130 potential indications that are appropriate for the saliva test. Some of the leading contenders for consideration include the following biometric tests:

- Cholesterol
- Prostate/PSA
- TORCH panel for pregnant women (Toxoplasmosis, Other agents, Rubella, Cytomegalovirus and Herpes simplex)
- HIV, AIDS
- Hepatitis B and C
- Luteinizing Hormone Test - thyroid, adrenal, pituitary, gynecological
- Personalized genetic diagnostics

[7] Pisanic, N., Randad, P. R., Kruczynski, K., Manabe, Y. C., Thomas, D. L., Pekosz, A., Klein, S. L., Betenbaugh, M. J., Clarke, W. A., Laeyendecker, O., Caturegli, P. P., Larman, H. B., Detrick, B., Fairley, J. K., Sherman, A. C., Rouphael, N., Edupuganti, S., Granger, D. A., Granger, S. W., Collins, M. H., … Heaney, C. D. (2020). COVID-19 Serology at Population Scale: SARS-CoV-2-Specific Antibody Responses in Saliva. *Journal of clinical microbiology*, *59*(1), e02204-20. https://doi.org/10.1128/JCM.02204-20

[8] Polymerase chain reaction

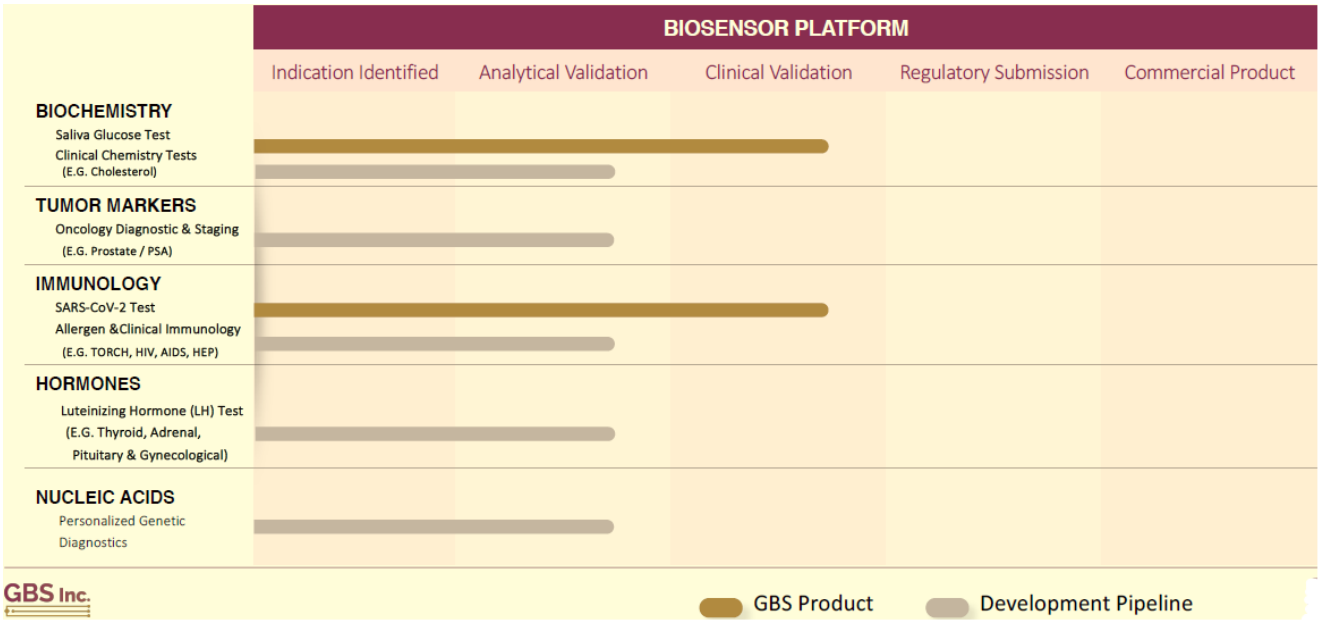
[9] Data from GBS press release, November 30, 2021. GBS Announces Plans for Clinical SARS-CoV-2 Antibody Trials.

[10] Pisanic, N., Randad, P. R., Kruczynski, K., Manabe, Y. C., Thomas, D. L., Pekosz, A., Klein, S. L., Betenbaugh, M. J., Clarke, W. A., Laeyendecker, O., Caturegli, P. P., Larman, H. B., Detrick, B., Fairley, J. K., Sherman, A. C., Rouphael, N., Edupuganti, S., Granger, D. A., Granger, S. W., Collins, M. H., … Heaney, C. D. (2020). COVID-19 Serology at Population Scale: SARS-CoV-2-Specific Antibody Responses in Saliva. *Journal of clinical microbiology*, *59*(1), e02204-20. https://doi.org/10.1128/JCM.02204-20

GBS Pipeline

In addition to the primary pursuits in saliva glucose test (SGT) and COVID, GBS has internally identified 130 real-time, non-invasive diagnostic tests appropriate for the biosensor platform technology. Below we include the company's pipeline which provides a summary and status of the clinical and early-stage programs underway.

Exhibit VI – GBS Pipeline[11]



[11] GBS Corporate Presentation, November 2021

Indications and Diagnostic Tests

Diabetes

With advancements in agriculture and supply chain, more food is available than ever before. While a victory over starvation, humans are unable to adapt to this surplus of accessible calories and medicine is struggling to catch up. According to the World Health Organization, global prevalence of diabetes in adults was an estimated 463 million between 2014 and 2019 and is rising quickly.[12] Type 1 diabetes is characterized by the inability for the pancreas to produce insulin whereas type 2 is marked by the body's resistance to insulin.[13] Prediabetes is identified by elevated blood glucose, but not to the threshold of diagnosis.[14] Diabetes can also occur in pregnant women, known as gestational diabetes, but it is frequently temporary. In 2017, the total cost of diagnosed diabetes was $327 billion in the US and $760 billion[15,16] around the globe.

Prevalence & Incidence

Global prevalence of diabetes in adults was 422 million in 2014, or approximately 8.5% of the population, almost double the relative prevalence in 1980.[17] Between 2014 and 2019, prevalence increased again to an estimated 463 million adults living with diabetes and is projected to rise to 700 million by 2045. Prevalence has risen rapidly in low- and middle-income countries versus high income countries. An estimated 79% of adults living with diabetes were living in low- and middle-income countries.[18] Prevalence of both type 1 and type 2 diabetes outpaces genetic variation, suggesting that environmental factors and behavior play a key role.[19]

Research conducted by Abuyassin and Laher in 2016 attribute the rise in diabetes to rapid urbanization, obesity, an increasingly sedentary lifestyle and dietary habits.[20] A statistical analysis finds significant correlation with sugar exposure. The region with the lowest prevalence of diabetes is in Africa, likely attributed to low urbanization and undernutrition.[21] The largest population of diabetics is in China, with approximately 116.4 million Chinese with the disease in 2019, followed by India, with a population of 77 million, and the United States at over 31 million.[22]

Risks

Prevalence of both type 1 and type 2 diabetes outpaces genetic variation, suggesting that environmental factors and behavior play a key role. Environmental factors that increase the risk of both types are diet, endocrine disruptors, environmental pollutants and even gut microbiome composition. It has been long accepted that diet and exercise are key behaviors that can affect blood sugar and A1C levels and that adjusting environmental factors can affect these critical inputs.[23] While there is a clear correlation between environmental factors and diabetes risk, causality remains to be established.[24]

Type 1: Factors related to the risk of type 1 diabetes are largely genetic, though trends in prevalence outpace that expected by genetic variation alone; discordance rates in twins, variation in geographic prevalence and urban migration also support the role of the environment in type 1 diabetes risk. The variability in onset age obscures the role of environment on childhood-onset type 1, but exposure to hazardous environments, even in the first few years, may contribute.[25] Other relevant environmental exposures include enteroviral infections, cereal/gluten, and low vitamin D serum concentration; perinatal exposure of nitrosamine has been implicated as well. Children with family history of type 1 diabetes, or have certain genes have increased risk of diabetes. Type 1 diabetes can appear at any age; however, the two most common age ranges are between 4-7 and 10-14 years old. While typically considered risk factors for type 2 diabetes, obesity and insulin resistance is now thought to be an accelerator of type 1 diabetes.[26]

[12] https://www.idf.org/aboutdiabetes/what-is-diabetes/facts-figures.html
[13] https://www.who.int/news-room/fact-sheets/detail/diabetes
[14] https://www.webmd.com/diabetes/what-is-prediabetes
[15] https://www.diabetes.org/resources/statistics/statistics-about-diabetes
[16] https://www.diabetesatlas.org/en/
[17] https://www.who.int/news-room/fact-sheets/detail/diabetes
[18] https://www.idf.org/aboutdiabetes/what-is-diabetes/facts-figures.html
[19] Skyler et al. 2017. Differentiation of Diabetes by Pathophysiology, Natural History, and Prognosis. *Diabetes*
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[22] https://www.diabetesatlas.org/en/sections/demographic-and-geographic-outline.html
[23] Wang, R.R., *et al.* Behavioral Science Research in Diabetes. Diabetes Care 2001 Jan; 24(1): 117-123.
[24] Skyler et al. 2017. Differentiation of Diabetes by Pathophysiology, Natural History, and Prognosis. *Diabetes*
[25] Skyler et al. 2017. Differentiation of Diabetes by Pathophysiology, Natural History, and Prognosis. *Diabetes*
[26] https://www.mayoclinic.org/diseases-conditions/type-1-diabetes/diagnosis-treatment/drc-20353017

Type 2: Risk factors related to type 2 diabetes mellitus include smoking, being overweight, insulin resistance, physical inactivity, family history, prediabetes, elevated A1C, high blood pressure, and high cholesterol.[27,28,29] Fat distribution throughout the body is correlated with type 2 diabetes risk. Those who store fat predominantly in the abdomen versus the hips and thighs are at higher risk.[30] Obesity and diabetes are related to abnormal sleep. Obstructive sleep apnea, often a result of obesity, can also shorten sleep duration and cyclically exacerbate the condition. Type 2 diabetes risk is also correlated with age, especially after age 45.[31] Race plays a role, with Black, Hispanic, American Indian and Asian-Americans at increased risk. While type 2 diabetes onset occurs at varying levels of obesity, Asians and Asian Americans can acquire type 2 diabetes at a lower body mass index.[32]

Symptoms & Diagnosis

Type 1: After losing β-cell function, type 1 diabetics experience hyperglycemia, symptoms of which include frequent urination, thirst, blurred vision, fatigue, irritability, hunger, and difficulty concentrating. Prolonged high blood glucose is implicit in the aforementioned risk to renal, neural, ocular, and cardiovascular systems. Metabolic markers, such as occurrence of dysglycemia can be used to monitor onset in at-risk individuals, and prediction accuracy can be further improved by tracking glucose and C-peptide.[33]

Type 2: The American Diabetes Associations recommends routine screening starting at the age of 45, especially if risk factors such as obesity, family history, or high blood pressure are present. Symptoms of type 2 diabetes, like type 1, include thirst, frequent urination, hunger, unexpected weight loss, fatigue, blurred vision, slow-healing sores, frequent infections and darkened areas of the skin around the armpits and neck. If left unchecked, type 2 diabetes can be deadly with atherosclerotic, neuropathic, renal, and ocular consequences. Also common is impaired healing that can render small cuts and blisters into infections that can require amputation. Auditory impairment, skin conditions and sleep apnea are all common, though obesity is thought to drive both sleep apnea and diabetes. Finally, patients with type 2 diabetes also are at increased risk of Alzheimer's disease, though the underlying mechanism is not understood. Type 2 diabetes is diagnosed the same way it is monitored, via glycated hemoglobin (A1C) test, which is an indicator of average blood sugar levels for the past few months. Other tests include the random blood sugar test, fasting blood sugar test and oral glucose tolerance test. The three are variants of common blood glucose testing. Blood glucose testing is not only used in diagnosis but also in the day-to-day management of diabetes.

Management & Treatments

Type 1: Management of Type 1 diabetes involves the injection of insulin to supplement the body's inability to produce its own. Under the care of a physician, an A1C goal is set and through insulin and meal-planning the condition is managed. Exercise and weight management are encouraged. Nutritional recommendations base the diet on higher levels of nutritious, low-fat, high-fiber foods and fewer animal products and refined carbohydrates. In addition to A1C, frequent blood-glucose monitoring is required in day-to-day management.[34]

Type 2: Disease progression can be slowed through medication and lifestyle intervention, and early therapy has demonstrated reduction in retinopathy, cardiopathy, and mortality. Insulin secretion deficiency can be partially rectified with caloric restriction and weight loss in early stages; it is difficult to reverse prolonged diabetes, even with dramatic intervention such as bariatric surgery, likely due to deterioration of β-cell function. Thus, early diagnosis and intervention is key to preserving β-cells. However, most patients, even after diagnosis of type 2 diabetes, are still exposed to years of hyperglycemia due to incomplete control.[35]

Diabetes type 2 is managed and treated through monitoring blood glucose and A1C, changes in lifestyle, taking drugs and supplementing insulin. Typically, the first line of defense for pre- and type 2 diabetes is change in lifestyle. Both aerobic and resistance training are recommended. Eating foods lower in fat and calories and higher in fiber, such as vegetables and fruits, daily aerobic activity and losing weight are encouraged.[36] Weight loss has been shown to improve insulin sensitivity in liver and skeletal muscle and may reduce fat accumulation in the pancreas.[37] Cessation of smoking is also recommended.[38] All of these factors can be guided by automated coaching and support.

[27] CDC National Diabetes Statistics Report 2020
[28] https://www.mayoclinic.org/diseases-conditions/type-2-diabetes/symptoms-causes/syc-20351193
[29] Skyler et al. 2017. Differentiation of Diabetes by Pathophysiology, Natural History, and Prognosis. *Diabetes*
[30] https://www.mayoclinic.org/diseases-conditions/type-2-diabetes/symptoms-causes/syc-20351193
[31] https://www.mayoclinic.org/diseases-conditions/type-2-diabetes/symptoms-causes/syc-20351193
[32] Skyler et al. 2017. Differentiation of Diabetes by Pathophysiology, Natural History, and Prognosis. *Diabetes*
[33] Skyler et al. 2017. Differentiation of Diabetes by Pathophysiology, Natural History, and Prognosis. *Diabetes*
[34] https://www.mayoclinic.org/diseases-conditions/type-1-diabetes/diagnosis-treatment/drc-20353017
[35] Skyler et al. 2017. Differentiation of Diabetes by Pathophysiology, Natural History, and Prognosis. *Diabetes*
[36] https://www.mayoclinic.org/diseases-conditions/type-2-diabetes/diagnosis-treatment/drc-20351199
[37] Skyler et al. 2017. Differentiation of Diabetes by Pathophysiology, Natural History, and Prognosis. *Diabetes*

Diabetes medication and insulin therapy are options as well. As foot ulcers in diabetics are common and can fester to the point of requiring amputation, management of type 2 diabetes also requires consistent hygiene and inspection of the feet. Physicians advise professional removal of foot-lesions, careful toenail trimming, avoiding going barefoot, and wearing shoes that fit properly. Conditions that require vigilance include ingrown toenails, blisters, plantar warts, bleeding/open sores, general inflammation, pain and foul odor.[39] Management of the risks of concurrent diabetes and tuberculosis involve screening, if either is suspected or diagnosed.

Frequent and consistent blood glucose monitoring is imperative for the care and management of both types of diabetes. Current standard of care is invasive, involving sometimes painful, and at the very least inconvenient finger pricks.

Diabetes Testing

An integral part of a diabetic's routine includes glucose testing. Blood sugar tests are required to ensure that levels are neither too high nor too low. Blood sugar levels of 200 or greater at any time and a fasting blood sugar level of over 125 indicate diabetes. Frequent testing for diabetics can help the individual manage their disease and select a diet and exercise that will reduce spikes in blood glucose levels. Diabetics and those prone to diabetes will normally test their blood glucose level at least once per day. Most individuals who test use a blood sugar meter which requires a lance, test strip and device. The lancet is used to prick the skin so that a small sample of blood is produced. The blood is placed on to the test strip which is then read by the blood sugar meter. Continuous blood sugar monitoring is another method used to monitor blood sugar. The associated device, a continuous glucose monitor (CGM), uses a sensor inserted under the skin which is in contact with interstitial fluid. The concentration of analytes in interstitial fluid constantly changes with glucose levels and the sensor wirelessly sends a reading to a monitor every few minutes. In some cases, the CGM is connected with an insulin delivery system so that blood sugar levels can remain within a predetermined range. One further test for diabetes is long term in nature called the hemoglobin A1C (HbA1c) test. It measures the amount of blood sugar attached to hemoglobin and shows the average blood sugar level over a trailing three-month period. HbA1c can be used to diagnose prediabetes or monitor the effectiveness of diabetes management.

SARS-CoV-2

Epidemiology

The majority of COVID-19 cases are asymptomatic or mild. The CDC estimates near 55 million cumulative cases in the US and global estimates of 290 million.[40] Deaths are estimated at almost 850,000 and 5.5 million respectively in the US and around the world. [41] Vaccines have become increasingly available to the public and this may have an effect on COVID-19 incidence. Progression of severe symptoms of COVID-19 appears to depend on the individual patient and their immune response. A subset of COVID-19 patients appears to be prone to cytokine release syndrome (CRS), also known as cytokine storm[42] which can be life threatening and cause organ failure.

Symptoms

Symptoms of COVID-19 include fever, dry cough and fatigue. Less commonly, patients experience aches, sore throat, headache, diarrhea, conjunctivitis, and loss of smell and taste.[43] In severe COVID-19, patients experience extreme difficulty breathing and shortness of breath. The resulting hypoxia produces symptoms of confusion, sweating, dizziness, hypotension and elevated heart rate as well as discoloration at the extremities due to lack of adequate tissue oxygenation.

Risk Factors

The CDC cites general COVID-19 risk factors as age, race/ethnicity, gender, certain medical conditions and medication use, poverty/crowding, certain occupations and pregnancy.[44] Regarding mortality, American Indian or Native Americans and Hispanic or Latino Americans are 2.4 and 2.3 times more likely to die from COVID-19 than white, non-Hispanic persons. Risk for death increases with age; those aged 85 and older are 7,900 times more likely to die than the reference population of 5-17 years of age.[45]

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[38] CDC National Diabetes Statistics Report 2020
[39] https://www.mayoclinic.org/diseases-conditions/diabetes/in-depth/amputation-and-diabetes/art-20048262
[40] Data as of January 2022. Source: https://www.worldometers.info/coronavirus/#countries
[41] Data as of January 2022. Source: https://www.worldometers.info/coronavirus/#countries
[42] Soy, M., Keser, G., Atagündüz, P., Tabak, F., Atagündüz, I., & Kayhan, S. (2020). Cytokine storm in COVID-19: pathogenesis and overview of anti-inflammatory agents used in treatment. Clinical rheumatology, 39(7), 2085–2094. https://doi.org/10.1007/s10067-020-05190-5
[43] Coronavirus (who.int)
[44] Assessing Risk Factors for Severe COVID-19 Illness | CDC
[45] Risk for COVID-19 Infection, Hospitalization, and Death By Age Group | CDC

Pathophysiology
COVID-19 results from an infection by the SARS-CoV-2 virus. Via the ACE2 receptor, SARS-CoV-2 infects the epithelial cells lining the respiratory tract using its spike proteins. ACE2 receptors are expressed on a variety of cells, including cells of the alveoli and even the digestive tract. Upon binding, the virus is endocytosed and translocated into endosomes, or fuses with the envelope of the host cell membrane. Upon entering, viral RNA is released into the cytoplasm of the host cell. A replication transcription complex is formed, driving production of copied viral RNA. Transcription of the replicated viral RNA produces mRNA. From this mRNA, the host cell facilitates the translation to create new viral proteins, which are then released into the surrounding cellular environment to infect other cells.

Standard of Care
There is no cure for COVID-19, only treatments to address certain aspects of the disease to either speed recovery, or to prolong survival. The FDA has approved remdesivir, an intravenous viral replication inhibitor (antiviral) and a combination of nirmatrelvir and ritonavir tablets for treatment of COVID-19. Results for the ACTT-1 trial of remdesivir in COVID patients were published in the *New England Journal of Medicine* and showed clinical benefit in recovery, and in mortality of patients receiving supplemental oxygen at 4% versus 13% on placebo.[46] However, the antiviral does not directly address the inflammation that is deadly in some patients.

Because COVID-19 has only recently emerged, many of the therapies available are in early stages of development. As inflammation is central to the pathology, many anti-inflammatory agents have been considered to combat advanced COVID-19, including chloroquine, hydroxychloroquine, JAK inhibitors, IL-6 inhibitors, IL-1 inhibitors, anti-TNF-alpha agents, corticosteroids, intravenous immunoglobulin, and colchicine.

In addition to drugs, patients with severe cases of COVID are typically administered supplemental oxygen and a mechanical ventilator to assist with breathing. Patients may lay in a prone position, facing downward, to facilitate breathing. Diuretics may also help to reduce the fluid buildup in the lungs.

Diagnosis
Any number of COVID-19 tests can be implemented to detect viral infection. Primarily, tests to detect the presence of the virus include RT-PCR, serology and antigen immune-assays. Reverse transcription polymerase chain reaction (RT-PCR) testing detects viral RNA using fluorogenic primers/probes, using thermal cycling and polymerase enzymes to amplify the RNA to a level where the fluorescent indicator can work.[47] Lateral flow immuno-assays flow sample across a membrane that is embedded with antigens that are specific to desired antibodies. Antibodies specific for the antigen bind to and remain at the site of the antigen and are identified using labeled detection antibody. Sample blood is collected and if anti-SARS-CoV-2 antibodies are present, they will bind to the flow-assay's reagent which can then be easily detected.

COVID-19 Testing

There are multiple testing approaches for SARS-CoV-2 which vary depending upon if the test is identifying an active infection or antibodies raised in response to the infection. To identify an active infection, a diagnostic, antigen or molecular test with material collected by nasal swab, throat swab or saliva is used. The primary test used to determine an active infection is a polymer chain reaction (PCR) test or Nucleic Acid Amplification Test (NAAT). Antigen tests also look for an active infection and use a nasal or throat swab to identify viral antigens associated with the virus. To test for an infection that has already occurred, an antibody or serology test draws a blood sample to determine if there was a past infection. The timing and type of antibody test affects accuracy. If testing is performed too early in the course of infection, when the immune response is still building up, the test may not detect antibodies.

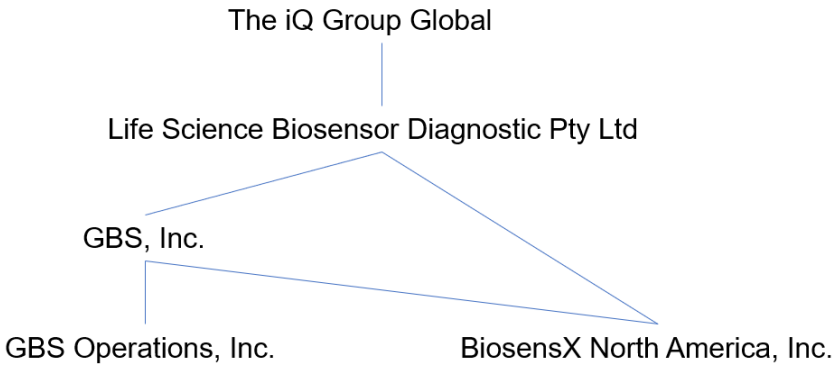
Tests for active infection can be divided into two groups: molecular tests and antigen tests. For both types a nasal or throat swab is taken and tested. Molecular tests look for the genetic material of the virus itself while antigen testing seeks to identify the outer proteins of the viral shell or envelope. Molecular tests are generally more accurate and usually processed in a laboratory, which takes longer. Antigen tests can be processed on-site such as a testing location, doctor's office, pharmacy or at home. Antigen tests generate results in about 15 minutes, but they tend to be less accurate than the tests run in the lab.

[46] Final report confirms remdesivir benefits for COVID-19 | National Institutes of Health (NIH)
[47] Shyu, D., Dorroh, J., Holtmeyer, C., Ritter, D., Upendran, A., Kannan, R., Dandachi, D., Rojas-Moreno, C., Whitt, S. P., & Regunath, H. (2020). Laboratory Tests for COVID-19: A Review of Peer-Reviewed Publications and Implications for Clinical Use. *Missouri medicine*, *117*(3), 184–195.

Ownership, Licensing, IP & Collaboration

On September 30, 2021, parent company Life Science Biosensor Diagnostics Pty Ltd (LSBD) owned 29.9% of GBS' outstanding common stock, down from 42.6% three months earlier. LSBD is both the owner of worldwide rights to the biosensor technology and the licensor of the Saliva Glucose Biosensor (SGB) and SARS-CoV-2 antibody test (COV2) platform. In May 2020, LSBD issued GBS 14 million shares of BiosensX, making GBS 50% owner in this entity that has rights to develop the glucose biosensor in North America.

Exhibit VII - GBS Ownership Hierarchy[48]

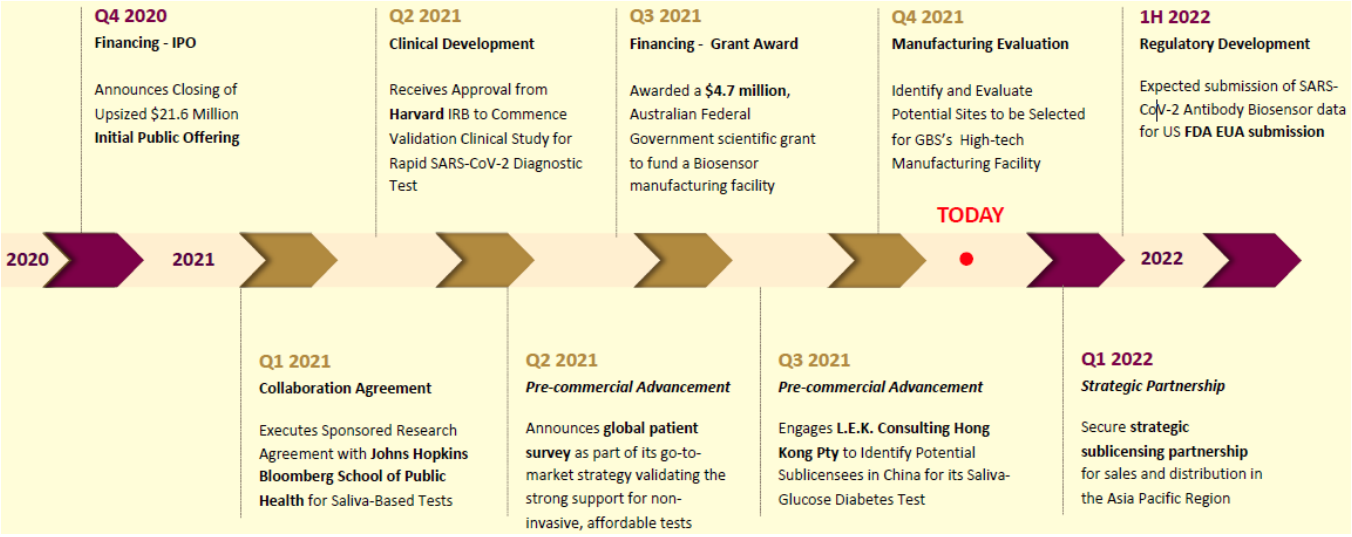


Milestones:

- GBS obtains worldwide rights for SARS-CoV-2 application - June 2020
- LSBD filed 513(g) submission with FDA for SGB to determine device classification - May 2020
- LSBD issues GBS 14M BiosensX shares - May 2020
- GBS enters into License Agreement with LSBD[49] for COV2 test - June 2020
- Glucose Biosensor Systems (Greater China) Pty Ltd renamed to GBS (APAC) Pty Ltd - October 2020
- GBS IPO - December 28, 2020
- Point of Care Test Commercialization
  - GBS and Harvard's Wyss Institute collaboration for COVID-19 announced - February 2021
  - Approval granted to start clinical studies on COVID-19 antibody biosensor
  - Gathered academic and scientific partners for test development & commercialization
- Glucose Monitoring Development
  - Clinical plan developed with Precision Medicine Architects
  - Study initiated at Johns Hopkins University and Bloomberg School of Public Health
  - Advancement of prototyping for middleware and smart phone application
  - Executed option agreement to commercialize saliva glucose biosensor in North America
- Option Agreement with LSBD and BiosensX to purchase rights to N. America - March 2021
- Australian government manufacturing facility grant - June 2021
- L.E.K. Consulting engaged to identify potential sublicensees - July 2021
- Pre-submission package filed with FDA for glucose biosensor - October 2021
- Clinical trial preparation for SARS-CoV-2 test - November 2021
- GBS & LSBD file application for saliva glucose test Breakthrough Device Designation - December 2021
- Results from the correlation, algorithm and collection studies for the glucose biosensor - 1Q:22
- Submission of COVID test for EUA - 1H:22
- Clinical study for glucose biosensor - 1H:22

[48] Image created by Zacks Analysts
[49] Life Science Biosensor Diagnostics Pty Ltd, who owns 42.6% of GBS common stock as of June 30, 2021

Exhibit VIII – Upcoming Milestones as of November 2021[50]



Intellectual Property

The biosensor technology that GBS has been licensed is protected by US patent 9,766,199. The patent is expected to expire in 2033. The technology is also protected in China under patent ZL201380022888.2 with both US and Chinese patents originating from the same Australian patent family. The assignee on the patent is Newcastle Innovation Ltd. The University of Newcastle, Australia initially developed Saliva Glucose Biosensor and handed off development to LSBD which then passed it on to GBS during its six year development life. The SGB program is currently in the validation stage which includes design and process development to verify and validate the final product. Commercial production of the biosensor will come online in order to clinically evaluate the product and seek regulatory approval. Another patent, also entitled Chemical Sensor, was granted in the United States in April 2021 with Paul Dastoor and Warwick Belcher credited as inventors. It describes the construction and composition of the transistor device and is numbered 10,978,653.

A second international patent application (PCT/AU2016/050555), titled Chemical Sensor, claims iterations to the device design and has been filed with a priority date of June 2016. It will soon enter national phase in certain jurisdictions, and further patent applications are in preparation. LBSD also filed an application in 2019 for Biosensor With Porous Wicking Layer (PCT/AU2019/050458) which describes the layered structure of the glucose biosensor.

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-fold lower than in blood.

Technology Licensing with LSBD

Saliva Glucose Biosensor Amended and Restated License Agreement
On September 12, 2019, GBS and licensor LSBD entered into an amended and restated license agreement for Saliva Biosensor Technology, which replaced the previous license agreement, and is limited to the Asia-Pacific (APAC) region and includes the following terms:

- The license is non-transferrable, non-assignable, non-sublicensable, royalty-bearing and fee-bearing;
- GBS may act as the regulatory authorization holder for the purpose of applying for and obtaining regulatory approval;
- GBS may promote, market, import into the Asia-Pacific (APAC) region, manufacture (including through an authorized supplier), offer, sell, and supply licensed products in the region, specifically for use in the region;
- GBS will provide customer support to end users and referring health care practitioners in the region for the licensed products;
- GBS will collect for LSBD biosensor data generated by the licensed products in the region.

[50] GBS Corporate Presentation, November 2021

Countries in the APAC region include Mainland China, Japan, Indonesia, Republic of Korea, Philippines, Vietnam, Malaysia, Bangladesh, Thailand, Taiwan, Australia, Hong Kong, Singapore, New Zealand, Myanmar, Cambodia, Lao People's Democratic Republic, Mongolia, Brunei Darussalam, Papua New Guinea, Fiji, New Caledonia, French Polynesia, Solomon Islands, Timor L'Este, Vanuatu, Kiribati, Marshall Islands, Tonga, Samoa, Federated States of Micronesia, Palau, Tuvalu, Nauru, Cook Islands, Niue and Tokelau.

Option Agreement with LSBD and BiosensX
On March 31, 2021, GBS entered into an option agreement with LSBD and BiosensX. BiosensX is owned both by LSBD directly and GBS, Inc., itself a subsidiary of LSBD, and is the holder of the technology license for the North American region. Under the terms of this agreement, LSBD granted GBS an exclusive option to purchase an exclusive license to use, make, sell and offer to sell products with its biosensor technology in the glucose/diabetes management field in North America. GBS is entitled to exercise the option at any time within two years from the effective date of the agreement by paying a $5 million fee to LSBD at the time of the option exercise.

Upon exercise, LSBD will transfer exclusive North American rights, and right to sublicense, to GBS that were originally assigned to BiosensX. If executed, the terms will also contain a commercialization milestone payment to LSBD for the equivalent of 5 years of royalties due 90 days from the end of the first royalty year.

COVID-19 Antibody Test
On June 23, 2020, GBS entered into a licensing agreement with LSBD for the use of the biosensor platform for COVID-19 applications. Included and described in the license are:

- a biosensor strip for antibodies against SARS-CoV-2;
- a proprietary smartphone application for the purpose of reading, storing, analyzing and providing patient support programs for any one or more of the indicators to measure immunoglobulin (IgG, IgM, IgA) concentration or amount specific to SARS-CoV-2;
- and/or 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 SARS-CoV-2.

Through the agreement, GBS obtained exclusive license to the COVID-19 biosensor technology worldwide and may:

- act as the authorized party when applying for and obtaining regulatory approval, including for the purpose of conducting clinical studies;
- manufacture, promote, market, import, offer, sell and distribute the licensed products;
- provide customer support to end users and health care practitioners;
- use the licensed products only for purposes identified in regulatory approval;
- collect data acquired from the licensed products.

Johns Hopkins Bloomberg, Diabetes/COVID-19

On February 18, 2021, GBS announced that it had executed a sponsored research agreement with Johns Hopkins Bloomberg School of Public Health to accelerate the development of next-generation saliva-based diagnostic tests. The collaboration between GBS and the Johns Hopkins Environmental Health Microbiology and Immunology Laboratory in the Development of Environmental Health and Engineering Salivary Biomarkers and Infectious Disease Program will inform GBS' commercialization strategy for two non-invasive, rapid, point of care diagnostic tests, SARS-CoV-2 antibody biosensor and saliva glucose biosensor. In 2020, research led by Johns Hopkins Environmental Health Microbiology and Immunology Laboratory demonstrated the potential utility of saliva testing in large-scale public health surveillance related to the COVID-19 pandemic. Saliva antibody responses were comparable to those observed in blood in individuals with COVID-19 as confirmed by RT-PCR.[51] GBS plans to work with Dr. Christopher Heaney, director of the Johns Hopkins Environmental Health Microbiology and Immunology Laboratory, and his team to identify new biomarkers best suited for testing via the saliva.

[51] Reverse transcriptase polymerase chain reaction, a genetic method of determining presence of SARS-CoV-2 virus, a proxy for SARS-CoV-2 infection

L.E.K. Consulting

This July, GBS enlisted the services of L.E.K. Consulting Hong Kong Pty Limited to identify suitable commercial partners for distribution in China. LEK promised to deliver and engage a shortlist of said potential partners within two months of starting. The arrangement with LEK builds on a recent global survey conducted by GBS to facilitate marketing efforts where GBS was, with key findings, able to support commercialization of a non-invasive alternative to current standard of care glucose monitoring. Sublicensing to a commercial partner in the China region will support GBS' initiative to make its saliva glucose biosensor test available to this rapidly increasing diabetic population. LEK was established in 1983 and is a global management consulting firm featuring deep industry expertise.

Wyss Institute, COVID-19

On December 1, 2020, GBS parent company, the iQ Group Global, first announced that it had licensed eRapid technology from Harvard's Wyss Institute to accelerate the development of COVID-19 diagnostics. On February 18, 2021, it was announced that GBS and the Wyss Institute would collaborate to validate and de-risk a specific and sensitive COVID-19 diagnostic that would integrate Wyss Institute's eRapid technology, which features low-cost; multiplexed detection of a broad range of biomarkers. Together the point-of-care COVID-19 diagnostic is envisioned to detect multiple SARS-CoV-2 biomarkers. On April 15, 2021, GBS announced that Harvard Longwood campus' Institutional Review Board (IRB) had approved the commencement of a validation study to test clinical samples from a COVID-19 repository. With approval from the IRB, the biosensors can now be tested on real, known samples for accuracy. Through the study, GBS and Wyss intend to validate the performance and feasibility of the jointly-produced assay leveraging Wyss' eRapid sensing platform built on GBS' biosensor strip.

On November 30, GBS announced that it will start preparations for SARS-CoV-2 antibody test clinical trials. The associated press release reiterated the primary findings of the study:

- The SARS-CoV-2 Antibody biosensor assay was 100% sensitive and 100% specific using positive and negative SARS CoV-2 human plasma samples;
- The time to obtain results was less than 10 minutes.

Next steps for development include the start of a clinical trial for the saliva SARS-CoV-2 antibody test and pursuit of an Emergency Use Authorization with the FDA for expedited approval of the test.

Biosensor Manufacturing Facility

On July 8, 2021, GBS announced the receipt of a grant from the Australian Federal Government's Department of Industry, Science, Energy and Resources' Modern Manufacturing Initiative to establish a high tech medical device manufacturing facility in Australia. The US$4.7 million grant will support the construction of the facility which will serve the APAC region. Government funding is expected to support approximately half of the total cost of the facility. Capacity of the facility may be up to 100 million units per year using reel-to-reel printing technology.

Financial and Operational Results

Fiscal Year 2021 Events

- Issued LSBD 5-year warrant[52] to purchase up to 3 million shares - December 2020
- Exchange agreement with LSBD to convert common shares to preferred stock[53] - December 2020
- LSBD preferred stock sold and assigned to institutional investor - December 2020
- $21.6M[54] IPO - December 2020
- Approval to commence validation clinical study for rapid COVID-19 test - April 2021
- Results from Global Glucose Monitoring Survey - June 2021
- $4.7M award from Australian Federal Government to build manufacturing facility - June 2021
- Pre-submission package for the glucose biosensor filed with FDA - October 2021
- Appointment of Dr. Steven Boyages as interim CEO - October 2021

Fiscal Year First Quarter 2021 Financial Results

GBS reported FY 1Q:22 results in a press release and filed its Form 10-Q with the SEC on November 11th and 12th respectively. No revenues were reported and operating expense totaled ($1.4) million producing a net loss of ($1.4) million or ($0.10) per share.

For the first quarter of fiscal year 2022 and versus the first quarter of fiscal year 2021, both ending September 30:

- General & Administrative expenses rose 156% to $1.3 million from $0.5 million on increase in operational activities following completion of the IPO;
- Development & Regulatory Approval expenses grew 245% to $107,000 from $31,000, driven by recent IPO funding that has allowed development to progress;
- Prospectus and capital raising expenses were zero vs. $166,000;
- Total operating expenses rose 117% to $1.4 million from $1.1 million;
- Net other income was *de minimis* vs ($414,000);
- Net loss including non-controlling interests was ($1.4) million vs. ($1.1) million or ($0.10) and ($0.12) per share, respectively.

As of September 30, 2021, cash and equivalents totaled $12.6 million. This amount compares to a $12.6 million at the end FY21 on June 30, 2021. GBS carries no debt on its balance sheet. Cash from operations was a positive $83,000 as the government grant receivable related to the manufacturing facility more than offset the net loss in the quarter. No financing cash flows were recognized.

Initial Public Offering

On December 28, 2020, GBS closed an initial public offering (IPO) selling 1,270,589 units at $17.00 per unit. Each unit consisted of one share of GBS common stock or Series B Convertible Preferred Stock at the purchasers election, one Series A warrant to purchase one common share at $8.50 per share with five-year expiry, and one Series B warrant to purchase one common share at exercise price of $17.00 also with a five-year expiry from issue date. Net proceeds from the offer totaled $17.7 million after deducting $1.7 million in underwriters' discount and commissions and $2.15 million in offering costs.

[52] 5-year warrant to purchase 3,000,000 shares of the Company's common stock at the exercise price of $17.00 per share to a maximum of $2 million over a 5-year period
[53] Series B Convertible Preferred Stock
[54] Gross proceeds

GBS claims on equity as of September 30, 2021:

- 14,882,522 of Issued Common Stock (as of November 8, 2021)
- 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 LSBD exercisable at $17.00

Australian Government Award for Manufacturing Facility

On July 8, 2021, GBS announced that it had received a US$4.7 million grant from the Australian Federal Government to fund the buildout of a biosensor manufacturing facility. The Australian government identified GBS' project as one of six National Manufacturing Priorities as a part of its Modern Manufacturing Strategy. The Strategy is a public-private initiative to develop Australian manufacturing infrastructure. The grant, deemed the Medical Products Priority Grant, will support the establishment of a medical device manufacturing facility for the scaled production of Printable Organic Electronic Biosensor technology for the Asia-Pacific (APAC) region. The manufacturing facility is expected to have capacity to produce 100 million biosensor units annually.

Global Voice of Customer Survey

GBS completed a global survey of more than 300 patients in June 2021. The survey was conducted to verify the desirability of GBS' saliva glucose biosensor and discuss daily life applications and features of the product candidate. The 300 patients worldwide, in key target markets, were living with diabetes and showed support for a non-invasive alternative to standard of care. 90% of patients responded positively to GBS' biosensor platform. Survey results revealed that 7 out of 10 patients indicated that they were 'seriously interested' in purchasing the product if released and 3 out of 10 wished to be placed on a waiting list ahead of release. US and China respondents differed in their pricing sensitivity, with US survey participants indicating that the price of a pain-free alternative would play a role in decision of whether to upgrade, while their Chinese counterparts indicated that price would not be an issue as long as the product was accurate and reliable.

Glucose Biosensor Pre-Submission Package Filed with FDA

On October 13, 2021, GBS announced that it had submitted its pre-submission package to the FDA to ensure that GBS' clinical plan is in line with the FDA's guidance. The pre-submission package will allow the FDA to review GBS' next steps, including clinical trial protocols, and provide feedback to GBS on any perceived challenges. GBS is undertaking a three-step clinical plan that begins with the generation of prospective data that tracks both salivary and blood glucose and the time relationship between the two, targeting enrollment of 20-40 subjects. GBS is finalizing arrangements with US clinical sites. Once the relationship between the saliva and plasma tests is established, the next phase will aim to develop the algorithm between the two then generate data for regulatory submission.

MANAGEMENT & LEADERSHIP

Dr. Steven Boyages MD, MB, BS, PhD. - Chairman of the Board and Chief Executive Officer

Dr. Boyages has served as Board Chairman for GBS since October 2020. He is a practicing clinical in endocrinology and current President of the World Hellenic Biomedical Association, and current Chairman of Specialist Information Services Pty Ltd. Dr. Boyages is also currently the CEO of Red Zeppelin, a Clinical Professor at University of Sydney and University of Western Sydney, and Director of the NSW Community Services and Health Industry Training Advisory Board.

Dr. Boyages previously held the position of Chief Executive of the Sydney West Area Health Service (SWAHS), which is now known as Western Sydney Local Health District. Covering a population of 1.2 million people, SWAHS employed more than 15,000 staff and had a gross operating budget of $2 billion (AUD), managing $1.6 billion (AUD) worth of assets. Dr. Boyages has also served as Medical Director for eHealth New South Wales, and was the foundation Chief Executive of the Clinical Education and Training Institute (CETI) New South Wales (NSW), Australia, set up to ensure the development and the delivery of clinical education and training across the NSW public health system. Prior to this, Dr. Boyages was the Director of Diabetes and Endocrinology at Westmead Hospital, from 1990 to 1999, during which time Dr. Boyages defined the pathophysiology of thyroid hormone deficiency on brain development secondary to iodine deficiency; developed prevention strategies in iodine deficient communities in China, India, Indonesia and Northern Italy; defined the impact of growth hormone excess and deficiency in adults and developed innovative population health models of care for people with diabetes. Dr. Boyages continues an active research career in a range of fields, centering on the pursuit of better models of chronic disease prevention and management.

Following this position, Dr. Boyages was the foundation director of the Centre for Research and Clinical Policy in NSW Health in 1999, during which he established the Priority Health Programs, doubled the Research Infrastructure Grants Program, established the Quality Branch of NSW Health and was appointed as Clinical Advisor to the Director General to implement the Government Action Plan for Health Reform. Additionally, Dr. Boyages was instrumental in establishing and securing funding for the NSW biotechnology strategy, BioFirst.

Dr. Boyages earned his Ph.D. in medicine and his MBBS from the University of Sydney.

Spiro Sakiris B.Bus, Dip Law, CA - Chief Financial Officer

Spiro Sakiris joined GBS in April 2019 as Chief Financial Officer. Sakiris brings over 30 years' experience in accounting and taxation, IPOs & capital raising and business system designs, including the application of IFRS and US GAAP for the life science industry. Mr. Sakiris is a member of the Institute of Chartered Accountants of Australia & New Zealand, a registered Series 28 principal with iQ Capital (USA) LLC and a registered broker-dealer with FINRA. He also serves as Special Projects Lead at The iQ Group Global. Sakiris holds a Diploma in Law from the LPA Board of NSW, and received his Bachelor of Business in accounting from the University of Technology Sydney.

Dr. Paul Dastoor, Ph.D., Scientific Board Member

Dr. Dastoor is a Professor in Physics in the School of Mathematical and Physical Sciences and the Director of the Priority Research Centre for Organic Electronics at the University of Newcastle in Australia. He received his B.A. degree in Natural Sciences from the University of Cambridge in 1990 and his Ph.D. in Surface Physics, also from the University of Cambridge, in 1995.

Dr. Dastoor's expertise covers surface analysis, electron spectroscopy, thin film growth, organic electronics, organosilane chemistry, polymer films, atom beam optics and microscopy and medical devices. His research can be grouped in three main areas: (1) Helium Atom Microscopy, (2) Polymer Adsorption on Metal Surfaces and (3) Organic Electronic Devices. Helium Atom Microscopy Atomic scattering from surfaces has matured into a unique analytical technique for the study of formation of thin film structures.

RISKS

All investments contain an element of risk which reflects business uncertainty and opportunity. Some investments exhibit higher predictability, with current, diversified cash flows and established sales. These enterprises will exhibit a lower level of perceived risk in contrast to other companies that are developing an undefined, new technology.

The diagnostic testing space includes companies at both ends of the spectrum, from mega-cap powerhouses such as Abbott and Roche that have dozens of established products, to small operations with a handful of employees conducting preclinical studies. Many of the risks faced by the large and small firms are similar; however, there are some hazards that are particular to smaller companies that have not yet established themselves or their products.

Pandemic Risk

The pandemic has disrupted economic and other activity in the United States and around the globe. It has also caused significant volatility in financial markets and disrupted clinical trials, regulatory actions and access to supplies. Access to capital has remained; however, risk perception may increase and financial markets may begin to reflect a lower level of economic activity and concerns over future availability of capital. Early-stage clinical firms lacking revenues rely on capital markets to sustain development efforts and may be sensitive to changes in risk perception and trading dynamics.

As the pandemic has progressed, disruptions to the supply chain and travel restrictions have affected firms around the globe. The risk of COVID variants, and difficulties in vaccinating a significant proportion of the population leave subsequent waves of infection as a possibility that may further impact corporate operations.

The FDA issued a press release and report regarding pandemic effects on the FDA's ability to conduct site inspections, necessary for marketing approval. The FDA reported that it had conducted 821 site inspections since March 2020, 777 of which were domestic. 68 were delayed. A delay in inspection shifts commercialization horizons; meanwhile, the company must continue to incur overhead costs for daily operations. In some cases, approvals have been delayed by the FDA due to travel related disruptions.

GBS is part of a subset of companies with technology that is applicable in combating the pandemic. In response to the pandemic, GBS is now developing, in collaboration with Harvard University, a real-time, point-of-care SARS-CoV-2 antibody biosensor. Risks to this include the ability of the biosensor to demonstrate high levels of sensitivity and specificity and for the technology to penetrate a market effective and reliable in detecting the antibodies, or for the antibody detection use case to diminish in demand.

Liquidity, Financing & Trading

Access to financing comes and goes in cycles. During periods of improving confidence and plentiful liquidity, capital may be easy to obtain; however, during a crisis or a period of heightened risk perception, even companies with bright prospects may be in trouble if they depend on the financial markets to fund their work. Pre-revenue biotech firms rely primarily on equity issuance to fund their operations. Funds can be sourced through debt or grants and tax credits; however, these sources may reduce the flexibility of the company and can create difficulties if debt is unable to be repaid. If capital is not readily available when needed, a company may be forced to suspend research and development, sell equity at a substantial discount to previous valuations and dilute earlier shareholders. A lack of funding may leave potentially promising therapies without a viable route forward or force a company to accept onerous terms. Trading volumes are lower for smaller biotech firms, creating liquidity risk for the investor and large transactions may have a material impact on share price. In periods of crisis or heightened risk perception, share price may be volatile. Companies with smaller capitalizations are typically considered riskier and changes in sentiment may adversely affect their trading prices and volumes. Smaller firms may also have less visibility, compete for investor dollars in a shallow market and be excluded from market indices.

GBS holds $12.7M as of September 30, 2021, which is expected to provide sufficient capital until the end of 2022. In June 2021, GBS was awarded $4.7M from the Australian Federal Government for the buildout of GBS' manufacturing facility which will offset about half the expected expenses for its construction. Following GBS' IPO in December of 2020, GBS former parent company, LSBD, owned approximately 54.4% of shares outstanding. Since then, the former parent has divested a material number of shares and as of September 30, 2021 owned 29.9% of shares outstanding. In an 8-K filed November 24, 2021, LSBD's rationale for the sale was provided. Shareholders may be at risk of continued parent company share sales.

Clinical Trials, Commercialization and Regulatory Burden

Investing in medical technology development is a lengthy process. The timeframe for conducting pre-clinical research to eventually commercializing using the *De Novo* route can take multiple years depending on the market and company-specific conditions. Regulatory oversight for diagnostic tests is required but can be less stringent as compared to implanted devices and pharmaceuticals. Biosensors do not enter the body and have an established evaluation process that can determine their accuracy and consistency. GBS' candidates, as saliva-based tests, may be evaluated via clinical trials more rapidly, due to their risk classification and transit to approval via the FDA's *De Novo* route. While the likelihood of success for a product transiting the *De Novo* pathway is greater than for drugs, there remains a possibility that the FDA will not approve.

Following LSBD's 513(g) submission to the FDA on May 1, 2020, it was determined that the *De Novo* application pathway for the Saliva Glucose Biosensor Diagnostic Test could be pursued. The *De Novo* pathway is for "novel medical devices for which general controls alone, or general and special controls, provide reasonable assurance of safety and effectiveness for the intended use, but for which there is no legally marketed predicate device."[55] Furthermore, GBS anticipates planning discussions with the FDA Office of In Vitro Diagnostics (IVDs) and Radiological Health, implying potential approval as an IVD. While the FDA provided the guidance suggesting a *De Novo* application, there still remains some risk that the *De Novo* application is not approved during Substantive Review. While a non-invasive biosensor is likely considered relatively safe, efficacy remains to be determined, and will be a critical component of the application to the FDA. The risk for the clinical trials is that the results do not support a compelling application to regulatory authorities.

GBS intends to market its glucose blood sensor in the Asia Pacific region, including China, and will be subject to risks of approval and commercialization in the Chinese market. Approval in China is granted via the National Medical Products Administration (NMPA), which has its own criteria and approval process. Furthermore, conducting business in China can be subject to government influence and interference.

If the sensor receives regulatory approval, GBS must then face the challenges and risks of commercialization. As no explicit permission to sublicense exists, GBS will manufacture and market its products using partners to aid in distribution in certain geographies. There are risks related to manufacturing, including maintaining consistency in device accuracy, as well as supply chain risks not limited to pandemic disruption. Perhaps the greatest risk is of market acceptance. The value proposition of a noninvasive blood glucose test is clear. However, the product still needs to win the endorsement of patients, physicians and other key opinion leaders.

Intellectual Property

Intellectual property is a fundamental pillar for technology companies. However, even with government regulation, patent protection is not guaranteed. The patent application process requires time, capital and the disclosure of substantial detail on the company's technology which is eventually made public. Despite submission of an application, patents may not be granted. Patent protection and enforcement requires legal resources that early-stage firms may not have. Furthermore, countries differ in the degree and type of intellectual property protection. Some firms may in- or out-license intellectual property, which exposes parties holding the patent to risk of adherence and litigation regarding the parameters of the licensing. Finally, patent protection is temporary and there is no guarantee that the firm will benefit from the patent protection before it expires.

GBS relies on multiple patents filed around the world for its intellectual property protection. Responsibility for patent applications and pursuit of patent infringement lies with the licensor, not with GBS. If the licensor does not attempt to enforce the patent, GBS is at risk for material loss of market share due to imitation products. Under terms of the license agreement, GBS has no right to compel the licensor to enforce patent protection. To this end GBS has retained certain art as trade secrets. However, the risk of trade secret theft, rediscovery, or circumvention via other innovation by competitors remains.

[55] De Novo Classification Request | FDA

Peers and Competitors

Glucose Blood Monitor Market & Competitors

GBS is targeting indications both in diabetes and COVID-19 with its saliva-based biosensor. GBS' biosensor will compete directly with, and attempt to replace, conventional finger-prick glucose blood monitors. GBS also envisions an Artificial Intelligence (AI) driven smartphone application that can collect user data and drive outcomes. Thus, GBS' peers and competitors will include glucose blood monitor companies, especially those that include app-based solutions.

The diabetes management space has experienced recent innovation as smartphones have become ubiquitous. Downloadable applications can track activity and diet and integrate with portable glucose testing and monitoring devices. The range of competitors is varied in size and features. Companies including Bayer, Abbott, Roche, Sanofi and Medtronic have sizable budgets and in-house manufacturing, distribution and sales forces. Others, like Livongo, now part of Teladoc (NYSE: TDOC), are substantially larger and have a more dominant footprint than GBS. These competitors are not manufacturers of test strips and could be customers for a saliva-based test strip.

Exhibit IX – Peers and Competitors[56]

Ticker	Company	Price	MktCap (MM)	EV (MM)	Therapeutic Area
950130	Access Bio	₩15,800	₩409,916	₩406,836	Rapid diagnostic tests: COVID, HIV, viral & other
ABT	Abbott Labs	$140.74	$248,869	$256,623	Blood analysis devices & software, rapid tests
BAYRY	Ascensia	$13.26	$52,108	$86,016	Blood glucose monitoring/diabetes management software
BDX	Becton, Dickinson	$251.48	$71,683	$86,391	Systems for culturing & specimen/blood collection
DRIO	Dario Health	$12.97	$215	$163	DTx for diabetes & other chronic conditions
DXCM	DexCom, Inc.	$536.95	$52,042	$51,048	Continuous glucose monitoring device and app
GOOG	Google Verily	$2,893.59	$1,920,661	$1,792,946	Miniaturized continuous glucose monitors with Dexcom
JNJ	Lifescan	$171.07	$450,358	$449,487	Blood glucose device and app
MDT	Medtronic plc	$103.45	$139,095	$154,033	Continuous glucose monitoring device and app
MOVE	Movano	$3.80	$125	$85	Wearable glucose & BP sensors
NMRD	Nemaura Medical	$4.56	$106	$88	SugarBEAT disposable glucose monitoring patch
NSTG	Nanostring Tech	$42.23	$1,928	$1,783	Biologic testing systems: nCounter & GeoMx
OTRK	Catasys	$6.29	$121	$83	Data predictive analytics, AI & telehealth services
RHHBY	Roche	$51.69	$353,043	$362,080	Blood glucose testing devices
SIEGY	Siemens	$86.60	$147,220	$184,683	Point of care testing: COVID & many other
SNY	Sanofi	$50.10	$126,331	$126,331	Blood glucose testing devices and app
TMO	Thermo Fisher	$667.24	$262,925	$272,586	Variety of COVID tests/Pathogen detection & analysis
TTOO	T2 Biosystems	$0.52	$86	$91	Rapid pathogen, biomarker & other detection w/ fluids
VIVO	Meridian Bioscience	$20.40	$885	$895	Test kits for viral & infectious diseases
VNRX	VolitionRx Limited	$3.14	$168	$148	Blood tests for diagnosing range of cancers worldwide
pvt	Medisana				Blood glucose device and app
pvt	Omada Health				App-based diabetes management
pvt	Onduo				Continuous glucose monitoring device/app diabetes mgmt
pvt	One Drop				Blood glucose testing device/supplies and app
pvt	Pops				Phone-mounted blood glucose testing device and app
pvt	Virta Health				App based diabetes monitoring and management
pvt	SG Diagnostics				Diagnostics in COVID, infectious disease & other
pvt	C8				Raman spectroscopy: non-invasively detect blood glucose
pvt	Rockley Photonics				Spectrophotometer-on-a-chip sensing module
pvt	DiaMonTech				Non-invasive blood glucose measurement
pvt	Creoptix Sensors				Uses grating coupled interferometry on biosensor
pvt	iKang Healthcare				Diagnostic testing
GBS	GBS Inc.	$140.74	$248,869	$256,623	Developing COVID & diabetes sensor tests

[56] Price and market capitalization data is as of December 31, 2021.

Valuation

Biosensors have evolved to accurately detect analytes in saliva as the supporting technology has become more precise. Organic thin film transistors provide not only greater sensitivity and specificity to detect desired analytes, but also offer a lower cost alternative that allows for new, more convenient sampling methods. The combination of greater sensitivity and reduced cost has opened a niche in the diagnostics market for a number of saliva-based tests.

GBS will initially be targeting two markets for its products including glucose sensors and COVID antibody detection. It is prioritizing approval and commercialization efforts in the Asia-Pacific (APAC) region and the US. We summarize the market opportunity in APAC by including the populations of China, Indonesia, Japan, Philippines, and Vietnam, noting that GBS' APAC license includes many other countries and territories.

We see the addressable market size of saliva strips matching that of blood glucose strips. The number of blood glucose strips used per year for diabetics varies widely depending on severity of the disease and a patient's personal preference. To guide our market size estimates, we relied on an IQVIA report that recorded 12.7 billion strips sold globally in 2016, with approximately 5.1 billion of those in the United States. We assume with improvements in health care penetration in the APAC region over the last six years, and its relatively large population of approximately two billion individuals, that there could reasonably be 5 billion test strips sold in the region per year. Following development in 2022 and 2023, we anticipate approval in the US and APAC regions and commercialization of the glucose biosensor in 2024.

We have identified at least 26 manufacturers of blood glucose test strips and systems ranging from megacaps such as Abbott Labs to small private firms such as One Drop. With this competitive environment as a guide, we estimate first year penetration (2024) of 50 basis points rising to 800 basis points by year eight (2031) in both North American and APAC markets. We assume per strip revenue[57] received by GBS of $0.40 in the United States and $0.20 in APAC. After adjustments for the LSBD royalty (13%) and cost of goods (2%), gross margin is estimated at 85%.

Based on a review of multiple sources of test volume data, we estimate that there will be approximately 450 million COVID tests in North America in 2022 and 1.21 billion in the rest of the developed world. As vaccination rates increase and herd immunity is approached, we see this number declining by 50% in 2023 and each year thereafter. We estimate that about 6% of these tests will be antibody tests, which represents the addressable market for GBS' COVID-19 antibody sensor, COV2T.

The FDA has approved over 400 COVID tests in the United States, including 88 antibody tests. We assume a multiple of this number has been approved in foreign jurisdictions, especially in APAC. Some of these are saliva tests, including one commercialized by Diabetomics called CovAb. Using the competitive environment as a barometer and the availability of the Emergency Use Authorization (EUA) pathway, we estimate a 20 basis point penetration into North American and developed markets globally in 2023. We estimate this to increase to 50 basis points of market share by year three (2025), where it will hold steady until demand for the COVID test dissipates. Revenue per test is forecast at $34 in North America and about $13.50 in the rest of the world with both rising at 3% per annum. Our guide for North America pricing is the Medicare reimbursement rate for a COVID test (CPT Code 86408) of about $42. In other markets around the world we assume a value 40% of this amount. Note that GBS will not be the ultimate seller of the product and will rely on partners and distributors to set the selling price and to remit an agreed upon fee to GBS upon sale that will be at a discount to the selling price. As compensation for their development work, we estimate that Harvard University will receive a 12% royalty for the COVID test. LSBD is owed an additional 13% royalty on sales to GBS. Cost of goods sold is modeled at a modest 2% yielding a 73% gross margin.

We model only sales of the strips themselves, and do not account for revenues that could potentially be generated via data, commercial adjacencies, product and services nor core operations synergy that management has cited as potential additional revenue generating channels. GBS' biosensors sit atop a platform technology that offers entry into a multitude of other diagnostic spaces. We think it possible and even likely that the value of saliva testing in oncology, metabolic diseases, immunology and other areas could be greater than GBS' initial foray into glucose and COVID. We will layer on these opportunities when they become clear and adjust the likelihood of success when the platform has proven itself commercially.

[57] While we calculate revenue on a per strip basis, most strips will be sold in lots of 50, 100 and 200.

Below the revenue and gross margin lines we estimate about $9.0 million in operational expenses in FY:22, $8.1 million in FY:23 and $10.6 million in FY:24, with 2023 and 2024 reflecting increasing amounts of selling and marketing costs. After 2024, we assume 3% inflation in development and regulatory costs and 5% for selling, general and administrative costs. Inflation for all operational costs is expected to be 3% in 2027 and after. Taxes are assessed at a 26% rate following the exhaustion of net operating losses.

Our valuation uses a discounted cash flow model adjusted for estimated probability of success. Assumptions include a discount rate of 15%, terminal growth of 0% and forecast of cash flow until 2043. Devices submitted to the FDA are approved at a relatively high rate and we forecast a 90% likelihood of regulatory success. To determine a per share price, we divide our DCF value by current shares of approximately 14.9 million, plus outstanding warrants of 7.3 million and other assumed issued shares of 10 million that represents a $20 million capital raise at $2 per share. This yields a valuation of $5.00 per share.

CONCLUSION

GBS Inc. offers a leading-edge technology that can simplify the diagnostic testing process and provide the base of a platform for easier and faster testing using saliva in a broad variety of areas. Initial opportunities in saliva-based testing of glucose and COVID antibodies, if successful, can be followed by others measuring tumor markers, hormones, nucleic acids and other analytes. Frequently-used diagnostic tests source a variety of biospecimens to identify desired analytes. This includes biopsies, blood, cerebrospinal fluid, urine and a variety of others, all of which are relatively inconvenient to collect and frequently require either medical assistance or special facilities. With the improvement of sensitivity of diagnostic testing combined with the low cost of OTFTs, a new option is emerging in saliva biosensors that is simpler, safer, easier and faster. GBS' first offerings in the space only require the individual being tested to place a strip in their mouth and use a point of care connected device to upload the results with output available in less than 10 minutes. No provider is needed to collect the specimen saving labor cost and exposure to disease, a benefit especially relevant during a pandemic.

Development, which has progressed over the last six years, has advanced to a stage where the technology is ready to enter the clinic. Preparation has also taken place in the marketing sphere and GBS has engaged a consultant to identify commercialization partners. Some potential partners have already been identified and we anticipate that when additional data on the accuracy of the technology is available, further steps will be taken here.

Both the glucose and COVID tests are undergoing clinical validation with registrational trials expected in calendar year 2022. If the COVID test is able to show sufficient accuracy, we expect an EUA submission, which is estimated to be granted supporting first commercialization in 2023. The glucose test is now undergoing a correlation, algorithm and specimen capture study prior to entering pivotal trials. We expect to see glucose studies begin in 2022 with results submitted to regulatory agencies in 2023 and marketing authorization granted in 2024.

While there are numerous competitors providing diagnostic testing, GBS' offering can potentially be a disruptor to the industry with its convenient, accurate, low cost and rapid solution. While still in the development stage, we think that if GBS is able to demonstrate superiority on each of these dimensions, it will quickly become an acquisition target for many of the large players in the device and related supplies testing space including Abbott Labs, bioMérieux, Roche and others. Even the laboratory companies such as Quest Diagnostics and LabCorp may be interested.

Key reasons to own GBS shares:

- **Organic thin-film transistor biosensor**
  - **Low cost**
  - **Easily produced**
  - **Accurate and sensitive**
- **Large addressable testing markets**
  - **Diabetes**
  - **COVID-19**
  - **Oncology Diagnostics & Staging**
  - **Luteinizing Hormone**
  - **Nucleic Acids**
- **Attractive research collaborations**
  - **Harvard's Wyss Institute**
  - **Johns Hopkins Bloomberg**
- **Commercialization rights to Asia-Pacific region including China**
- **Option to purchase rights to North American region**
- ***De Novo* application pathway**

Based on our analysis and review of GBS' technology and tests we see global penetration of its glucose and COVID tests over the next several years. Our work takes into account the relative valuation of each program in North America and APAC combined with our estimate of regulatory success to generate a price target for GBS' equity shares. The sum and conclusion of our work which rely on our model and assumptions discussed herein generate a valuation of $5.00 per share.

PROJECTED FINANCIALS

GBS Inc. - Income Statement

GBS Inc.	2021 A	Q1 A	Q2 E	Q3 E	Q4 E	2022 E	2023 E	2024 E
Total Revenues ($US ,000)	**$1,980**	**$0**	**$0**	**$0**	**$0**	**$0**	**$1,939**	**$17,492**
Gross Margin	$1,980	$0.0	$0	$0	$0	$0	$1,416	$10,232
General & Administrative	$3,359	$1,333	$1,200	$1,000	$1,100	$4,633	$5,200	$6,000
Development & Regulatory	$3,836	$107	$1,250	$1,400	$1,600	$4,357	$5,500	$6,000
Other	$359	$0	$0	$0	$0	$0	$0	$0
Income from operations	($5,573)	($1,439)	($2,450)	($2,400)	($2,700)	($8,989)	($8,761)	$5,492
Operating Margin	*-281%*	*# DIV/0!*	*# DIV/0!*	*# DIV/0!*	*# DIV/0!*	*# DIV/0!*	*-452%*	*31%*
Net Interest Expense	($1,080)	$5	$0	$0	$0	$5	$0	$0
Other Items	($407)	($3)	$0	$0	$0	($3.1)	$0	$0
Non-controlling Interest	($23)	$0	$0	$0	$0	$0.0	$0	$0
Net Income	**($7,037)**	**($1,438)**	**($2,450)**	**($2,400)**	**($2,700)**	**($8,988)**	**($8,761)**	**$5,492**
Net Margin								
Reported EPS	**($0.68)**	**($0.10)**	**($0.16)**	**($0.16)**	**($0.18)**	**($0.60)**	**($0.26)**	**$0.16**
YOY Growth								
Basic Shares Outstanding	10,415	14,006	14,900	15,220	15,350	14,869	34,000	35,000

Source: Company Filing // Zacks Investment Research, Inc. Estimates

HISTORICAL STOCK PRICE

GBS Inc. – Share Price Chart[58]

[58] Source: Zacks Research System

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