

# SQI DIAGNOSTICS INC.

Management's Discussion and Analysis of Financial Condition and Results of Operations

For the three months ended December 31, 2021

## Management's Discussion and Analysis of Financial Condition And Results of Operations

This Management's Discussion and Analysis ("MD&A") of the financial condition and results of operations of SQI Diagnostics Inc. (the "Company" or "SQI") is for the three months ended December 31, 2021. It is supplemental to, and should be read in conjunction with, the unaudited interim financial statements for the Company for the three months ended December 31, 2021 and 2020 which is available on SEDAR at www.sedar.com.

All amounts are expressed in Canadian dollars unless otherwise indicated. All financial data presented in this MD&A for the three months ended December 31, 2021 is unaudited. Unless the context otherwise requires, references in this MD&A to the "Company", "SQI", "we", "us" or "our" refers to SQI Diagnostics Inc. and its subsidiaries.

This MD&A was approved by the board of directors of the Company on February 25, 2022 and was prepared by management using information available as of such date.

### Cautionary Note Regarding Forward-Looking Statements

This document contains forward-looking statements that relate to future events or future performance and reflect our expectations and assumptions regarding our growth, results of operations, performance and business prospects and opportunities. Such forward-looking statements reflect our current beliefs and are based on information currently available to us. In some cases, forward-looking statements can be identified by terminology such as "our goal", "may", "would", "could", "will", "should", "expect", "plan", "intend", "anticipate", "believe", "estimate", "predict", "potential", "continue", "positioned" or the negative of these terms or other similar expressions concerning matters that are not historical facts. The forward-looking statements in this document include, among others, statements regarding our future operating results, economic performance, product development efforts, and statements in respect of:

- our requirement for, and our ability to obtain, future funding;
- *our expected future losses and accumulated deficit levels;*
- technological advances of competitive products and general market competition;
- *our expectations regarding the acceptance of our products by the market;*
- our expectations regarding the progress and the successful and timely completion of the various stages of the regulatory clearance process, including with respect to the development, viability and commercialization of our TORdx LUNG product; EXACT COVID-19 Antibody Test, the RALI-Dx<sup>TM</sup> and the RALI-fast<sup>TM</sup> products;
- our expectations regarding the progress and the successful and timely completion of the various stages of the regulatory clearance process;
- our strategy to develop new products and to enhance the capabilities of existing products;
- our strategy with respect to research and development;
- our dependence on expanding our customer base;
- our ability to obtain a sufficient supply of the components needed for our products;
- our ability to respond to legislative changes in the healthcare environment;

- *our plans to retain and recruit personnel;*
- our ability to develop and manufacture product to meet customer demands
- our plans to correct defects or errors in our systems; and
- our strategy with respect to the protection of our intellectual property.

A number of factors could cause actual events, performance or results, including those in respect of the foregoing items, to differ materially from the events, performance and results discussed in the forward-looking statements. Factors that could cause actual events, performance or results to differ materially from those set forth in the forward-looking statements include, but are not limited to:

- uncertain future capital needs and additional financing;
- history of losses;
- *market competition;*
- market acceptance of products;
- complex regulatory compliance requirements;
- rapidly changing technology and customer requirements;
- research and development activities;
- *marketing and distribution;*
- reliance on key suppliers;
- legislative or regulatory change;
- key personnel;
- development or manufacturing delays;
- unknown defects or errors;
- *foreign exchange fluctuations;*
- intellectual property protection;
- the economic effects of a pandemic, endemic or outbreak of an infectious disease, including, but not limited to, COVID-19;
- the impact of COVID-19 on our results;
- uncertainty surrounding regulatory approval for the Company's COVID-19-related testing products;
- volatility of share price and an active market for our shares;
- unanticipated impacts of the PBI Acquisition (as defined below);
- other risks detailed from time-to-time in our ongoing quarterly filings, annual information forms, annual reports and annual filings with applicable securities regulators, and those which are discussed under the heading "Risk Factors".

Although the forward-looking statements contained in this management discussion and analysis are based on what we consider to be reasonable assumptions based on information currently available to us, there can be no assurance that actual events, performance or results will be consistent with these forward-looking statements, and our assumptions may prove to be incorrect. These forward-looking statements are made as of the date of this document.

#### **COMPANY OVERVIEW**

SQI is a leader in the science of lung health and a developer of COVID-19 related testing products. We develop and manufacture respiratory health and precision medicine tests that run on SQI's fully automated systems. Our tests simplify and improve COVID-19 antibody monitoring, Rapid Acute Lung Injury testing, donor organ transplant informatics, and immunological protein and antibody testing. We're driven to create and market life-saving testing technologies that help more people in more places live longer, healthier lives.

### Research and Development Activities / Product Pipeline

As a science-driven company, SQI brings rigor, discipline and data-driven decision-making to every aspect of our work. That is how we developed some of the world's most advanced respiratory testing and organ health technologies, and that will continue to be our focus going forward. Since the start of the COVID-19 pandemic, we have also been focused on making and marketing life-saving testing technology that puts health back in people's hands.

The EXACT COVID-19 Antibody Test measures the IgG, IgM and IgA antibodies of SARS-COV-2 in people who have been infected with COVID-19, people who have been vaccinated or asymptomatic people wanting to know if they have been exposed. The test is more than 99% accurate and results are delivered in 24-48 hours after a sample is delivered to our New York State partner service laboratory, KSL Diagnostics Inc. As previously disclosed, the Company anticipates filing with the New York State Department of Health ("NYSDOH") for approval of the use of the EXACT COVID-19 Antibody Test and collection kit in the first calendar quarter of fiscal year 2022. If the EXACT COVID-19 Antibody Test receives NYSDOH approval, the test is expected to be available as a direct-to-consumer product which would help people avoid travelling to a clinic or hospital to be tested for the presence of the SARS-COV-2 antibodies. If licensed SQI intends to distribute this test through Azova, Inc. ("AZOVA"), its distribution partner in the United States. There can be no assurances as to when the EXACT COVID-19 Antibody Test will receive NYSDOH licensure or if it will receive such licensure at all.

The RALI-Dx<sup>TM</sup> IL-6 Severity Triage Test and the RALI-*fast*<sup>TM</sup> IL-6 Severity Triage POC Test each help clinicians identify which patients with SARS-CoV-2 are predicted to have a severe inflammatory response and should or should not be admitted to the hospital. Both tests measure the critical biomarker IL-6, which plays a key role in the cytokine storm phase of the COVID-19 disease. RALI-Dx<sup>TM</sup> delivers results from the lab in less than an hour while RALI-*fast*<sup>TM</sup> delivers results at the patient point-of-care in about 15 minutes. As previously disclosed, the Company applied for an Interim Order from Health Canada for the RALI-Dx<sup>TM</sup> IL-6 Severity Triage Test in the first quarter of fiscal year 2022 and currently expects to apply for an Interim Order for RALI-*fast*<sup>TM</sup> in fiscal year 2022. There can be no assurances as to when the RALI-Dx<sup>TM</sup> IL-6 Severity Triage Test or the RALI-*fast*<sup>TM</sup> IL-6 Severity Triage POC Test will receive Health Canada approval or if the tests will receive such approval at all.

SQI is also pioneering an advanced diagnostic test, the  $TORdx^{TM}$  LUNG test, aimed at increasing the chance of successful lung transplant by assessing the health of the donor organ before transplant surgery. The  $TORdx^{TM}$  LUNG test helps transplant surgeons assess a donor lung's

suitability for transplantation by measuring inflammation at the molecular level to assess the health of donor lung, enabling surgeons to transplant healthy lungs that otherwise would have been rejected. To the knowledge of the Company, there is currently no other such test approved for this intended use in the US or Canada. The Company has initiated and conducted pre-submission discussions with the FDA, and these regulatory discussions have been slowed by the FDA's focus on COVID-19 relevant submission reviews; the Company expects to restart the FDA dialogue when COVID-19 submission backlog subsides.

Upon receipt of regulatory approval from the FDA and Health Canada of the  $TORdx^{TM}$  LUNG Test, clinical development is planned for diagnostic tests designed to increase the chance of successful kidney and liver transplant.

Our partnership with University Health Network (UHN) relating to lung transplant research is one of our most established and important collaborations and we look forward to continuing our pioneering work with UHN to improve the lives of transplant patients. UHN is increasing the procurement, stabilization and transportation of healthy donor lungs available for transplant by supporting perfusion centers across North America. Implementation of Ex-Vivo Lung Perfusion (EVLP) procedures (FDA approved in 2019) has enabled lung transplant centers to increase the availability of donor lungs for transplant by nearly two-fold at some centers. Upon receipt of FDA market approval for the TOR $dx^{TM}$  LUNG Test, SQI intends to leverage its product offering within the EVLP market and direct to transplant hospitals. The Company is currently waiting for the FDA to shift its attention to non-COVID-related products before proceeding with the completion of final clinical studies for regulatory submission.

Although COVID-19 has led to certain regulatory and clinical challenges, we remain focused on our organ transplant pipeline of products. Subsequent to the end of the first quarter of fiscal 2022, SQI signed a non-binding product development and commercialization agreement with Owlstone Medical, a UK-based early disease detection and precision medicine company, which could assist to expand our lung transplant segment of our business into the post-transplant monitoring market.

Under the autoimmune disease testing segment of our business, SQI has an approved direct-to-consumer Celiac Disease and a Rheumatoid Arthritis (RA) Test that help users to assess the likelihood of developing disease. These tests have been sold through one of our distribution partners in the US.

## **Business Strategy**

SQI continues to make new acquisitions and position itself for growth in new lines of business in the human diagnostics field. We are working to attract a broader array of new customers, to engage in more cross-selling opportunities and use accretive acquisition to support the aggressive launch of our lung health products.

To optimize its human and financial resources, the Company's planned go-to-market strategy for its COVID-19 EXACT Antibody Test is to fully leverage its partnership with AZOVA (<a href="www.azova.com">www.azova.com</a>). AZOVA is changing the way consumers access healthcare. Through AZOVA's globally connected digital health system, consumers can access a wide range of

healthcare services including telehealth, behavioral health, vaccinations, medication management and laboratory testing services. AZOVA has also pioneered the COVID Credentials<sup>TM</sup> Health Pass, an electronic vaccination record source verification service. This service provides an electronic and globally shareable vaccination record for anyone to use for back to work, back to school, and back to travel. We believe our COVID-19 EXACT Antibody Test will be a significant driver for our testing business.

Our business strategy is to become a rapid diagnostics leader by maximizing our research and development, our product offerings and our testing-services platforms. Our current revenue streams are focused on advanced diagnostics that target COVID-19 testing, organ transplant, and autoimmune disease. We believe the consumer market wants access to convenient, accurate rapid diagnostic healthcare tests. Our development and marketing strategy includes:

- Successful clinical development completion and regulatory approval of our diagnostic products
- Successful marketing and sales of our DTC and B2B diagnostic tests via strategic business partnerships such as our recent agreement with AZOVA
- Expanding our commercial testing revenues and operations in the U.S. via partner labs KSL Diagnostics Inc and Immco Diagnostics
- Upgrading our Toronto manufacturing infrastructure to produce up to four million tests annually including our EXACT COVID-19 Antibody tests. The Company currently has capacity to produce up to one million tests annually
- Acquiring key talent to build our business
- Exploring in-licensing and out-licensing of technologies and products such as our recently announced partnership with Owlstone Medical
- Developing new products that complement our offerings through research and development

Our strategy of merging innovative diagnostics with differentiated health management services helps us to comprehensively support health care professionals, patients, and consumers across the globe.

We are adopting industry best practices in clear, straightforward external communications and sharpening our messaging to clarify our mission. We are focused on the timely and transparent communication of product announcements, company hires, partnerships and other material information about the Company.

### INTERIM MD&A QUARTERLY HIGHLIGHTS

## Financial Highlights for the Quarter

Revenues during the Company's first quarter of fiscal 2022 (\$59,000) were lower than revenues in the same quarter in the previous year (\$161,000). The decrease was due to a combination of factors including a production equipment issue that impacted shipment of products during the quarter and a strategic pivot away from the Lifesciences business. The Company intends to focus on its larger revenue markets in lung health, which includes the EXACT COVID-19 and RALI line of products and their respective testing business.

Major operating expenses during the Company's first quarter of fiscal 2022 included corporate & general, sales & marketing and research and development (R&D) costs.

Corporate and general expenses during the Company's first quarter of fiscal 2022 were lower (\$1,584,000) as compared to the previous year quarter (\$1,688,000). The decrease was mainly due to lower professional fees for consultants and lower stock-based compensation expense in the current year quarter. In the prior year quarter, the Company relied on services from external consultants to help facilitate the submission of its products for regulatory approval and commercialization efforts. Most of those contracts ended before the beginning of the first quarter of fiscal 2022. Stock-based compensation expense was higher in the first quarter of fiscal 2021, due to higher stock options expense for the former CEO. In the first quarter of fiscal 2022, stock-based compensation expense for the current CEO which was lower due to a difference in the number of stock options granted as well as a difference in the vesting periods associated with those options.

R&D costs during the Company's first quarter of fiscal 2022 were lower (\$1,696,000) as compared to the previous year quarter (\$1,838,000). The reduction in R&D expenses was a result of lower R&D consulting and supplies costs. In the prior year quarter, there was a higher than usual number of R&D activities to support regulatory submission which resulted in higher consulting and supplies costs.

### **Reconciliation of Use of Proceeds from Financing Activities**

In November 2021, the Company completed a non-brokered private placement of an aggregate of 26,932,895 units of the Company at a price of \$0.19 per unit for gross proceeds of approximately \$5,100,000 (the "November Private Placement"). Each such unit was comprised of one common share of the Company and one common share purchase warrant. Each such warrant is exercisable at a price of \$0.25 per share and entitles the holder thereof to acquire one common share for a period of five years from the date of issuance. Of the units issued pursuant to the November Private Placement, the Controlling Shareholders subscribed for an aggregate of 21,052,631 units for gross proceeds of approximately \$4 million. The issuances of units to such Controlling Insiders were considered related party transactions. For additional details please see the material change report of the Company, as amended, dated December 1, 2021, which is available on SEDAR at <a href="https://www.sedar.com">www.sedar.com</a>.

The following table reconciles the Company's actual versus identified use of proceeds from financing activities:

	Intended Use of Proceeds from November Private Placement	Estimated Use of Proceeds from November Private Placement	Variance
Employee salaries	1,720,000	\$1,719,582	\$418
and benefits			

Product R&D and manufacturing	613,000	613,104	(\$104)
expenses			
Purchase of	1,291,657	1,290,183	\$1,474
equipment,			
biological reagents			
and consumable			
materials			
Interest on	225,343	225,343	-
Debentures			
General working	1,250,000	1,251,788	(\$1,788)
capital			
Total	5,100,000	\$5,100,000	-

In addition to the foregoing, on December 31, 2020 the Company disclosed that the \$4 million of proceeds raised from the exercise of certain common share purchase warrants by the Controlling Shareholders was expected to be used for the Company's product commercialization and manufacturing programs, sales and marketing and for general working capital purposes. The Company confirms that all such proceeds have been used as at the date of this MD&A. The funds were expended as follows: (i) approximately \$1.7 million on employee salaries and benefits; (ii) approximately \$0.5 million on product R&D and manufacturing expenses; (iii) approximately \$1 million on purchase of equipment, biological reagents and consumable materials; and approximately \$0.8 million on general working capital.

### SELECTED FINANCIAL INFORMATION

### **Quarterly Metrics and Analysis**

The table below summarizes quarterly financial information for the three months ended December 31, 2021.

	Three months ended Dec 31, 2021 (000s)	Three months ended Dec 31, 2020 (000s)
Revenue	\$59	\$161
Net Loss	\$(3,434)	\$(3,718)
Net Loss per share	\$(0.01)	\$(0.01)
Weighted Average Shares	380,144	309,530

#### Revenues

During the three-month period ended December 31, 2021, the Company recorded revenue from the sale of custom kits and service revenue. The table below summarizes revenue by category.

	Three months ended Dec 31, 2021 (000s)	Three months ended Dec 31, 2020 (000s)	
Product Sales - Kits	\$16	\$104	
Service Revenue	\$43	\$57	
	\$59	\$161	

*Three months:* 

#### **Product Sales – Kits**

Sales revenue in the first quarter of fiscal 2022 was lower due to a malfunctioning of manufacturing equipment which impacted shipments during the quarter. In addition, there were no shipments of Rheumatoid Arthritis (RA) kits as the Company has undertaken a design change to improve product performance. There was also a reduction in kits revenue for the *RALI-Dx*<sup>TM</sup> product, which in the first quarter of fiscal 2021 was being shipped to UHN for testing before its submission to the FDA. Since submission to FDA, which took place in fiscal year 2021, there have been no shipments of RALI-Dx in the current year quarter, thereby decreasing revenue.

#### **Service Revenue**

Service revenue comprises lease revenue, maintenance services and processing fees for test kits.

Service revenue in the first quarter of fiscal 2022 was lower than it was in the first quarter of fiscal 2021. The reduction in service revenue is due to the Company's decision to pivot away from the Lifesciences business and focus on other products in its portfolio resulting in no sales for the first quarter of fiscal 2022. In first quarter of fiscal 2021, approximately 72% of the Company's service revenue was derived from customers in the Lifesciences business. The Company expects to receive nominal revenue, if any, from this segment of its business going forward.

#### **Net Loss**

#### Three months:

For the quarter ended December 31, 2021, the Company recorded a net loss of \$3,434,000 (\$0.01 net loss per share) as compared to a net loss of \$3,718,000 (\$0.01 net loss per share) in the quarter ended December 31, 2020.

The net loss was lower in the first quarter of fiscal 2022 primarily due to lower corporate and general, sales and marketing and R&D expenses. These expenses were higher in the first quarter of fiscal 2021 due to an increase in activities to support regulatory submissions. Additionally, the former CEO was still employed by the Company during this period resulting in higher stock-based compensation. In the first quarter of fiscal 2022, a significant portion of the work related to regulatory submissions had been completed or near completed, resulting in lower R&D expenses. Sales and marketing expenses also decreased due to a reduction in headcount resulting from the departure of the Company's Vice President of sales. The Company is recruiting to replace this position.

### **Liquidity and Balance Sheet**

Management expects further investments in our planned R&D programs, Clinical and Regulatory programs, product development and commercialization efforts for our pipeline of custom consumable kits, new products and platforms, and sales and marketing initiatives for the remainder of fiscal 2022.

The Company believes it has sufficient capital to operate and execute its business plan through the next quarter. Factors that will affect our future anticipated cash requirements include but are not limited to: (i) costs associated with our infrastructure development for a US sales network, our clinical development and research activities and the regulatory decisions by the NYSDOH and Health Canada; and (ii) our ability to attract and receive additional financing.

Operating activities for the quarter ended December 31, 2021 were financed by cash on hand.

As of December 31, 2021, current assets were \$4,844,000 including \$3,377,000 of cash compared to \$5,797,000 of current assets that included \$5,086,000 of cash as of December 31, 2020. As of December 31, 2021, the Company had a \$2,733,000 working capital surplus compared to a surplus of \$3,532,000 as of December 31, 2020.

Cash used in investing activities for the quarter ended December 31, 2021 was \$507,000 as compared to \$42,000 for the quarter ended December 31, 2020. Cash used in investing activities was spent on automation equipment designed to significantly increase manufacturing throughput and on additional equipment to increase capacity to support near term commercialization of products sufficiently advanced through the regulatory process.

The Company has a principal amount of approximately \$2.5 million of outstanding long-term debentures (the "Debentures") with an interest rate of 10%, which will mature in approximately four years. An aggregate of approximately \$2.1 million principal amount of the outstanding Debentures is held, directly or indirectly, by the Controlling Shareholders.

### **Subsequent to the Quarter**

Acquisition of assets from Precision Biomonitoring Inc.

On February 14, 2022, the Company, through with its wholly-owned subsidiary SQI Diagnostics Systems Inc. ("SQI Systems"), completed the announced acquisition (the "PBI Acquisition") of

substantially all of the assets underlying Precision Biomonitoring Inc.'s ("PBI") human diagnostic COVID-19 PCR testing business and its TripleLock<sup>TM</sup> molecular diagnostic testing technology (together, the "PBI Business") for aggregate consideration of \$6,825,000 consisting of \$6,145,000 in cash and 4,171,779 common shares of the Company at a deemed price of \$0.163 per share with an aggregate deemed value of \$680,000. In addition, on closing of the PBI Acquisition, SQI acquired certain PBI Business inventory for a total cash purchase price of \$616,243. The PBI Acquisition was completed pursuant to the terms of an asset purchase agreement dated January 10, 2022 entered into among the Company, SQI Systems and PBI.

To assist the Company with the funding of the cash consideration paid under the PBI Acquisition, the Company entered into a credit agreement with Pivot Financial ("Pivot"), an arm's length third party, with respect to the extension of a short-term senior secured demand credit facility in the aggregate amount of \$7,500,000 (the "Credit Facility"). The Controlling Shareholders participated in funding 50% of the aggregate amount advanced under the Credit Facility. The Credit Facility matures two months from the date of closing and bears interest at a rate of 15% per annum. No commission or bonus was paid in connection with extension of the Credit Facility, and the Credit Facility is not convertible into any securities of the Company. The Credit Facility has been secured by a first charge general security interest over the Company, as borrower, and the Company's wholly owned subsidiary SQI Systems, as guarantor. In connection with the extension of the Credit Facility, the lenders under the Credit Facility were paid a facility fee in the amount of \$320,000.

The participation of the Controlling Shareholders under the Credit Agreement was considered a related party transaction. For additional details please see the material change report of the Company dated February 24, 2022, which is available on SEDAR at www.sedar.com.

Signed Memorandum of Understanding (MOU) with Owlstone Medical

Consistent with our partnering strategy, on January 24, 2022, the Company announced that it signed a Memorandum of Understanding with Owlstone Medical, a UK-based early disease detection and precision medicine company, pursuant to which the SQI and Owlstone Medical may partner to develop and commercialize non-invasive, breath-based detection of fungal lung infection and transplant rejection.

## **Outstanding Capital Stock**

As of the date of this MD&A, there were 393,635,000 common shares issued and outstanding.

The following tables describe the securities that have been issued that are convertible under certain conditions into common shares: The Company had the following warrants outstanding as at the date of this MD&A:

Number of Warrants (000s)	Exercise Price	Maturity
1,388	\$0.21	March 10, 2022
26,018	\$0.20	December 20, 2022 – August 24, 2023
12,344	\$0.17	July 12, 2024
32,300	\$0.13	September 25 and October 22, 2024

622	\$0.085	February 20,2025
44,444	\$0.12	February 14, 2025, and March 5, 2025
26,933	\$0.25	November 1, 2026 and November 8, 2026
144,049		

The Company had the following stock options outstanding under its stock option plan of the date of this MD&A:

Number of Options (000s)	Range of Exercise Prices	Weighted average time to maturity
1,372	\$ 0.07 - 0.14	3.00 years
23,778	\$ 0.15 - 0.22	3.69 years
1,455	\$ 0.23 - 0.30	8.50 years
26,605		·

Options granted to Mr. Andrew Morris, CEO, are included in the table above. These options are performance-based, which vest as the Company achieves certain milestones, including amounts of funds raised, revenues achieved, share price appreciation and receiving regulatory approval for certain products under development.

### **Off-Balance Sheet Arrangements**

The Company has no off-balance sheet arrangements.

### CRITICAL ACCOUNTING POLICIES AND SIGNIFICANT ESTIMATES

The Company's financial statements are prepared in accordance with International Financial Reporting Standards ("IFRS").

The significant accounting policies that management believes are the most critical in fully understanding and evaluating the reported financial results are included in the interim financial statements for the quarter ended December 31, 2021. Refer to the interim financial statements for the quarter ended December 31, 2021 for discussion on accounting policies and estimates that are most important in assessing, understanding and evaluating the Company's interim consolidated financial statements. Changes in these estimates and assumptions could have a material impact on the Company's interim consolidated financial statements.

## **Risk Factors**

An investment in our common shares involves several risks. In addition to the other information contained in this Management Discussion and Analysis, including our consolidated financial statements and related notes for the quarter ended December 31, 2021, investors should consider the following risk factors. Any of the matters highlighted in these risk factors could have a material adverse effect on our business, results of operations and financial condition, causing an investor to lose all, or part of their investment.

The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties that we are not aware of or focussed upon, or that we currently deem to be immaterial, may also impair our business operations and cause the trading price of our common shares to decline

### Risks Related to Pandemics, Epidemics or outbreak of infectious diseases

The economic effects of a pandemic, epidemic or outbreak of an infectious disease could adversely affect our operations or the market price of our Common Shares

Public health crises such as pandemics, epidemics or similar outbreaks could adversely impact our operations or the market price of our Common Shares. In December 2019, COVID-19 was reported to have surfaced in Wuhan, China and has reached multiple other countries, resulting in government-imposed quarantines, travel restrictions, school closures and other significant restrictions on business operations imposed by governmental authorities in North America, Europe and worldwide. On January 30, 2020, the World Health Organization declared the outbreak of the COVID-19 a "Public Health Emergency of International Concern." On January 31, 2020, U.S. Health and Human Services Secretary Alex M. Azar II declared a public health emergency for the U.S. to aid the U.S. healthcare community in responding to COVID-19, and on March 11, 2020, the World Health Organization characterized the outbreak as a "pandemic". The extent to which the COVID-19 impacts our operations or market price of our securities will depend on future developments, which are highly uncertain and cannot be predicted with confidence, either internationally or within the U.S. or Canada, including the duration of the outbreak, new information that may emerge concerning the severity of the COVID-19 and the actions to contain the virus or treat its impact, among others. COVID-19, however, has already resulted in significant volatility in the world and the national trading markets.

The ongoing spread of COVID-19 may impact our operations, including a sustained delay in returning to the number of lung transplants performed pre-COVID-19. Our existing and potential customers such as Biopharma companies may redirect resources away from current research and or product development priorities to COVID-19. The spread of an infectious disease, including COVID-19, may also result in the inability of our suppliers to deliver components or raw materials on a timely basis or at all. The significant spread of COVID-19 within the U.S. and Canada resulted in a widespread health crisis and has had adverse effect on the national economies generally, the markets that we serve, our operations and the market price of our securities.

### Impact of COVID-19 on Our Results

During the quarter ended December 31, 2021, the Company's sales were adversely impacted by COVID-19 due to restrictions currently in place at certain customer sites. It is anticipated that revenues will continue to be adversely impacted in fiscal 2022 until these restrictions are lifted and operations return to normal. In particular, the Company's kit sales to one of its major customers have declined.

During the quarter ended December 31, 2021, the Company participated in the Canada Employment Wage Subsidy and Biotalent Student Work Placement program, where payments of

\$175,000 and \$26,000 were received under these programs respectively to partially offset employee wages during the period.

## Uncertainty surrounding regulatory approval for the Company's COVID-19 related products

The Company has several new products awaiting approval by US and Canadian regulatory authorities, including its COVID-19-related portfolio of products. There has been no firm timeline established for approval for the products, and the authorities can change their priorities at any time, deprioritizing the Company's products without notice. This would negatively impact the Company's financial performance and may impact the share price.

## **Risks Related to Intellectual Property**

## **Intellectual Property Protection**

Our commercial success depends, in part, upon our ability to protect our intellectual property and proprietary technologies and upon the nature and scope of the intellectual property protection the Company receives. We rely on patent protection, where appropriate and available, as well as a combination of copyright, trade secret and trademark laws, and nondisclosure, confidentiality and other contractual restrictions to protect our proprietary technology. However, these legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage.

We may be involved in litigation or other proceedings to protect or enforce our patents and proprietary rights, to determine the scope, coverage and validity of others' proprietary rights, or to defend against third party claims of intellectual property infringement, and the cost to the Company of any litigation or other proceedings, even if resolved in our favour, could be substantial.

The ability to compete effectively and to achieve partnerships will depend on the Company's ability to develop and maintain proprietary aspects of the its IVD Products and to operate without infringing on the proprietary rights of others. The presence of such proprietary rights of others could severely limit its ability to develop and commercialize its IVD Products, to conduct its existing research and could require financial resources to defend litigation, which may exceed the Company's ability to raise such funds. There is no assurance that the Company will be able to obtain patent protection of its IVD Products, related product reference designs and trade secrets in a form that will be sufficient to protect its intellectual property and gain or keep any competitive advantage that the Company may have.

The patent positions of biotechnology companies can be highly uncertain and involve complex legal, scientific and factual questions for which important legal principles remain unresolved. Patents issued to the Company may be challenged, invalidated or circumvented. To the extent the Company's intellectual property offers inadequate protection, or is found to be invalid or unenforceable, the Company is exposed to a greater risk of direct competition. If its intellectual property does not provide adequate protection against the Company's competitors' products, its competitive position could be adversely affected, as could the Company's business, financial condition and results of operations. Both the patent application process and the process of

managing patent disputes can be time consuming and expensive, and the laws of some foreign countries may not protect the Company's intellectual property rights to the same extent as do the laws of Canada and the United States.

The Company will be able to protect its intellectual property from unauthorized use by third parties only to the extent that they are covered by valid and enforceable intellectual property rights including patents or are effectively maintained as trade secrets, and provided the Company has the funds to enforce its rights, if necessary.

### **Risks Related to Our Common Shares**

### Volatility of Share Price

Securities markets have a high level of price and volume volatility, and the market price of securities of many companies have experienced wide fluctuations in price which have not necessarily been related to the operating performance, underlying asset values or prospects of such companies. As a result, the market price of our common shares at any given point in time may not accurately reflect the long-term value of the Company.

#### Active Market

There can be no assurance that an active market for the common shares will develop or be sustained. If an active public market for the common shares does not develop, the liquidity of a shareholder's investment may be limited and the share price may decline.

### Dividends and distributions

To date, we have not paid any dividends and do not expect to do so in the foreseeable future. We currently intend to retain all future earnings for the operation and expansion of our business. Dividends on our common shares are declared at the discretion of our board of directors and will depend on our results of operations, capital requirements, financial condition, prospects, contractual arrangements and other factors that our board determines are relevant.

### Control Risk

As at the date of this MD&A, our three Controlling Shareholders own, or exercise control of direction over, directly or indirectly, in aggregate, greater than 75% of our outstanding common shares, namely (i) Cumberland Private Wealth Management Inc., which, together with Cumberland Investment Counsel Inc. and Gerald R. Connor, a director, beneficially owns, directly or indirectly, and/or exercises control or direction over an aggregate of 98,791,107 common shares representing approximately 25.10% of our issued and outstanding common shares, of which Mr. Connor beneficially owns, directly or indirectly, and/or exercises control or direction over 97,729,790 common shares, representing approximately 24.83% of the issued and outstanding common shares (ii) Clive J. Beddoe, a director, according to information provided by him, beneficially owns, directly or indirectly, 99,046,865 common shares representing approximately 25.16% of the issued and outstanding common shares and (iii) Wilmot L. Matthews, also a director, according to information provided by him, beneficially owns, directly or indirectly,

100,408,488 common shares representing approximately 25.51% of the issued and outstanding common shares. Individually, each of the foregoing individuals are capable of controlling and or exerting significant influence over the direction of the Company and therefore have the ability to determine the outcome of most corporate actions or decisions requiring the approval of our shareholders. The interests of our Controlling Shareholders may conflict with those of our other shareholders.

## Risks Related to the PBI Acquisition

The success of the PBI Acquisition will depend, in part, on the ability of the Company to realize the anticipated benefits from integrating the PBI Business into the business of the Company. If the Company is not able to achieve these objectives, or is not able to achieve these objectives on a timely basis, the anticipated benefits of the PBI Acquisition may not be realized fully or at all. In addition, the actual integration may result in additional and unforeseen expenses, which could reduce the anticipated benefits of the PBI Acquisition, and may also result in additional and unforeseen matters that require the attention of management, which could divert management's focus and the Company's resources from other strategic opportunities and operational matters. There can be no assurances that the Company will not incur additional material costs in subsequent quarters to reflect additional costs associated with the PBI Acquisition or that the benefits expected from the PBI Acquisition will be realized. Failure to successfully integrate the PBI Business for any of these reasons could have a material adverse effect on the Company's business, financial condition and results of operations.

# Disclosure Controls and Procedures, and Internal Control Over Financial Reporting

The accompanying audited financial statements have been prepared by management in accordance with International Financial Reporting Standards. For quarterly reporting periods, the Company's interim financial statements are approved by the Audit Committee and the Board of Directors. For annual reporting periods, the Company's financial statements are approved by the Board of Directors upon recommendation by the Audit Committee. The integrity and objectivity of all financial statements are the responsibility of management. Also, management is responsible for all other information in this report and for ensuring that this information is consistent, where appropriate, with the information contained in the interim financial statements.

In support of this responsibility, management maintains a system of internal controls to give reasonable assurance as to the reliability of financial information and the safeguarding of assets.

In particular, the CEO and CFO or his designate are responsible for establishing and maintaining disclosure controls and procedures ("DC&Ps") and internal controls over financial reporting ("ICFRs") for the Company, and have:

- (a) designed such DC&Ps, or caused them to be designed under supervision, to give reasonable assurance that material information is made known during the period in which the annual and quarterly filings are being prepared;
- (b) designed such ICFRs, or caused them to be designed under supervision, to give reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with IFRS;

- (c) evaluated the design and effectiveness of the Company's DC&Ps as of December 31, 2021;
- (d) have concluded that a material design weakness in the ICFRs may exist in terms of the inadequate segregation of certain duties, which is typical of development stage companies; mitigating factors, including dual-payment authorization policies and transparent internal financial transaction reporting processes, serve to minimize the risk that such design weakness could result in a material misstatement of results for the year ended December 31, 2021; and
- (e) have concluded that, other than the item described above in sub-point (d), there are no additional material design weaknesses in the DC&Ps or ICFRs, and that the effectiveness of the DC&Ps is sufficient to expect the prevention or detection of material misstatements of results.

The audited financial statements include amounts that are based on the best estimates and judgments of management. The Board of Directors is responsible for ensuring that management fulfills its responsibility for financial reporting and internal control. The Board of Directors exercises this responsibility principally through the Audit Committee. The Audit Committee consists of three directors, all of whom are not involved in the daily operations of the Company and one of whom is independent. The Audit Committee meets with management and the external auditors to satisfy itself that management's responsibilities are properly discharged and to review the interim financial statements before their presentation to the Board of Directors for approval.

### **Glossary of Terms:**

**Biomarker:** Biological molecules, the presence or absence of which can be used to detect or monitor a state of disease or can be used to test the efficacy or safety of a drug in development

FDA: United States Food and Drug Administration

**Multiplex(ing):** to obtain multiple results from one single biological sample to save time, cost and development of multiple tests

**PCR:** Polymerase Chain Reaction

**R&D:** Research and development

sqidlite<sup>™</sup>: Our bench-top diagnostic system – fully automated bench top microarray processing system

 $\mathbf{sqid}$ - $\mathbf{X}^{^{\mathsf{TM}}}$ :  $\mathbf{sqid}$ - $\mathbf{X}^{^{\mathsf{TM}}}$  System – semi-automated bench-top platform that incorporates all of SQI's technology with the exception of automated fluidics handling

**TripleLock:** Is a qPCR testing platform in a 96-well plate format, leveraging shelf-stable, lyophilized chemistry that enables quick and accurate testing for defined DNA or RNA targets