



**SQI DIAGNOSTICS INC.**

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

**September 30, 2021**

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

*This Management's Discussion and Analysis ("MD&A") covers the annual financial statements of SQI Diagnostics Inc. (the "Company" or "SQI") for the years ended September 30, 2021 and 2020. The annual audited financial statements and MD&A for the year ended September 30, 2021 can be found on SEDAR at [www.sedar.com](http://www.sedar.com).*

*All amounts are expressed in Canadian dollars unless otherwise indicated.*

*This discussion and analysis were prepared by management using information available as of January 25, 2022.*

*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 EXACT COVID-19 Antibody Test, the RALI-Dx™ and the RALI-fast™ 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;*
- *the completion of the closing of the PBI Acquisition (as defined herein), including the financing of its cash consideration, and expected impacts of such acquisition;*
- *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 have been developed to simplify the diagnostic testing process, including with respect to 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 are also 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 > 99% accurate and results are delivered in 24-48 hours following sample delivery to our New York State partner service laboratory. 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 second 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 allow people to avoid travelling to a clinic or hospital to be tested for the presence of the SARS-COV-2 antibodies.

The RALI-Dx™ IL-6 Severity Triage Test and the RALI-*fast*™ 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™ delivers results from the lab in less than an hour while RALI-*fast*™ delivers results at the patient point-of-care in about 15 minutes. The Company applied for an Interim Order from Health Canada for RALI-Dx™ 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*™ in fiscal year 2022.

We also remain focused on our organ transplant pipeline of products. SQI is pioneering an advanced diagnostic test that increases the chance of successful lung transplant by assessing the health of the donor organ before transplant surgery. The Company's TORdx™ LUNG Test measures inflammation at the molecular level to assess the health of the donor lung, enabling surgeons to transplant healthy lungs that otherwise would have been rejected; there is currently no other such test. Upon receipt of regulatory approval of the TORdx™ LUNG Test, clinical development is planned for diagnostic tests designed to increase the chance of successful kidney and liver transplant.

SQI's clinical research partner at University Health Network (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 TORdx™ LUNG Test, SQI intends to leverage its product offering within the EVLP market and direct to transplant hospitals.

Under autoimmune disease testing, 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.

## **Business Strategy**

To optimize available human and financial resources, the Company's planned go-to-market strategy for products in development is to leverage its partnership with Azova Inc. ([www.azova.com](http://www.azova.com)) to the fullest extent possible. 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 initial 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 Inc.
- Expansion of our commercial testing operations in the U.S. via partner labs
- Upgrading our Toronto manufacturing infrastructure to produce up to 4 million EXACT COVID-19 Antibody tests annually
- Acquisition of key talent to build our business
- Potential in-licensing and out-licensing of technologies and products such as our recently announced partnership with Owlstone Medical
- Additional development of new products that complement our offerings through research and development

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

We are committed to improving the quality of our external communications and sharpening our messaging to clarify our mission and are focused on the timely and transparent communication of product announcements, company hires, partnerships and other material information relating to the Company.

## **Business Highlights During the Quarter**

### **COVID-19 EXACT Antibody Test**

During the quarter, the Company worked diligently on its application for pre-Emergency Use Authorization (EUA) for the EXACT COVID-19 Antibody Test with the US Food and Drug Agency (the “FDA”). In the first quarter of fiscal 2022, the FDA announced that due to changes to the nature of the COVID-19 pandemic it had moved into a new phase with respect to testing and was no longer prioritizing the review of at-home testing and home sample collection for COVID-19 antibody tests under EUA. As a result of these changes, the Company decided to pursue an alternate regulatory pathway and expects to submit its EXACT COVID-19 Antibody test to the NYSDOH for regulatory approval, which the Company expects to receive in the second quarter of fiscal year 2022. Such approval would give us the opportunity to distribute our product all over the United States.

### **Appointment of new CEO**

On September 11<sup>th</sup>, 2021, Andrew Morris, a member of the board of directors of SQI, was formally appointed as the Company’s CEO, replacing Clive Beddoe, who acted as interim CEO.

### **Financing:**

Historically, funding for our business has been done primarily through the issuance of units consisting of common shares and warrants. A significant percentage of the outstanding common shares and warrants of the Company are held by three insiders of the Company who are also Board members and control persons (collectively, the “**Controlling Shareholders**”).

### **Financial Highlights for the Quarter**

Revenues during the Company’s fourth quarter of fiscal 2021 (\$143,000) were lower than revenues in the same quarter in the previous year (\$251,000). This reduction is a result of higher research related revenue for its RALI-Dx™ IL-6 Severity Triage Test kits and higher revenues from the Lifesciences business. In the fourth quarter of fiscal 2020, the Company worked in partnership with UHN and shipped kits to them for its RALI-Dx™ IL-6 Severity Triage Test, to complete the research and testing required for submission to FDA. The submission to FDA took place in March 2021, therefore, there was no further research related revenue recognized for RALI -Dx™ IL-6 Severity Triage Test in the fourth quarter of fiscal 2021.

Major operating expenses during the Company's fourth quarter of fiscal 2021 included research and development (R&D) costs, with clinical expenses increasing as the company prepared to submit the application for its EXACT COVID-19 Antibody Test for regulatory approval to NYSDOH, with an expectation to complete the submission in the second quarter of fiscal year 2022. The majority of the increase in R&D costs came specifically from spending on clinical studies relating to RALI-Dx™ IL-6 Severity Triage Test & EXACT COVID-19 Antibody Test as SQI used strategic partnerships with various vendors and consultants and executed on a sponsored research agreement with the University of Buffalo.

Corporate and general expenses during the Company's fourth quarter of fiscal 2021 were lower (\$874,000) as compared to the previous year quarter (\$1,630,000). The decrease was mainly a result of several expenses that were present in the previous year quarter that were not present in the fourth quarter of fiscal 2021, including a write-down of inventory (\$154,000) related to a dispute with a customer of the Company higher legal fees (\$200,000) to form a US-subsiary and fees relating to the hiring of Robert Chioini as the Company's former CEO (\$184,000). Quarterly stock option expense was \$260,000 lower in the Company's fourth quarter of fiscal 2021 compared to the same prior year period due to expense associated with the grant of stock options to Mr. Chioini in the fourth quarter of fiscal 2020 same period last year

## SELECTED FINANCIAL INFORMATION

### Quarterly Metrics and Analysis

The table below summarizes quarterly financial information for the three months and twelve months ended September 30, 2021.

	Three months ended Sept 30, 2021 (000s)	Three months ended Sept 30, 2020 (000s)	Twelve months ended Sept 30, 2021 (000s)	Twelve months ended Sept 30, 2020 (000s)
Revenue	\$143	\$251	\$917	\$1,023
Net Loss	\$(2,600)	\$(2,815)	\$(10,557)	\$(8,571)
Net Loss per share	\$(0.01)	\$(0.01)	\$(0.03)	\$(0.03)
Weighted Average Shares	338,454	266,943	338,454	266,943

### Revenues

During the three-month and twelve-month period ended September 30, 2021, the Company recorded revenue from the sale of custom kits, as well as service revenue to our biopharma and diagnostic customers. The table below summarizes revenue by category.

	Three months ended Sept 30, 2021 (000s)	Three months ended Sept 30, 2020 (000s)	Twelve months ended Sept 30, 2021 (000s)	Twelve months ended Sept 30, 2020 (000s)
Product Sales - Kits	\$70	\$138	\$462	\$568
Product Sales - Platform	-	-	-	\$98
Service Revenue	\$73	\$113	\$455	\$357
	<u>\$143</u>	<u>\$251</u>	<u>\$917</u>	<u>\$1,023</u>

*Three months:*

### **Product Sales – Kits**

Sales revenue in the fourth quarter of fiscal 2021 were lower as most research related revenue for RALI-Dx™ IL-6 Severity Triage Test had been recognized in fiscal 2020 in the first two quarters of fiscal 2021. The Company completed its FDA submission for its RALI-Dx™ IL-6 Severity Triage Test product in March 2021.

### **Service Revenue**

Service revenue in the fourth quarter of fiscal 2021 was lower than it was in the fourth quarter of fiscal 2020. The revenue recognized in the current year quarter came from a combination of R&D development work, processing of celiac and RA samples, lease of equipment and maintenance fees. In Q4 2020, approximately half of the revenues came from R&D development work for one customer (\$63,000), which did not recur in the current year quarter, thereby explaining the decrease. The remainder of the revenues recognized was consistent with those in the current year quarter: maintenance contracts and lease of equipment.

*Twelve months:*

### **Product Sales – Kits and Platform**

Sales revenue in fiscal 2021 was \$462,000 compared to \$666,000 in fiscal 2020. Overall kit sales were consistent year over year, however the major difference in revenues came from decreased sales to UHN in fiscal 2021 that were predominantly RALI-Dx™ related with a year-over-year decrease of approximately \$104,000. The reduction in RALI-Dx™ related revenue was primarily a result of RALI-Dx™ research activities took place in 2020 and the first two quarters of fiscal 2021, with the submission of the RALI-Dx™ IL-6 Severity Triage Test taking place at end of second quarter of fiscal 2021. The majority of the Company's research-related revenue was recognized in fiscal 2020.

In fiscal 2020, there was one platform sale (\$98,000) with no corresponding sale in fiscal 2021.



## **Service Revenue**

Service revenue in fiscal 2021 was \$455,000 as compared to \$357,000 in fiscal 2020. The increase in year-over-year service revenues was a result of increased sales in the Life Sciences sector, with one customer contract accounting for approximately \$63,000 of such increase. The balance of the increase was due to marginal increases in maintenance contract revenue and processing revenues from other customers.

## **Net Loss**

### *Three months:*

For the quarter ended September 30, 2021, the Company recorded a net loss of \$2,600,000 (\$0.01 net loss per share) as compared to a net loss of \$2,815,000 (\$0.01 net loss per share) in the quarter ended September 30, 2020.

The net loss was lower in the fourth quarter of fiscal 2021 mainly due to lower corporate and general expenses. As mentioned above, the lower corporate expenses were due to lower legal fees, lower stock option expenses and the absence of inventory write-offs in the quarter.

### *Twelve Months:*

For the year ended September 30, 2021, the Company recorded a net loss of \$10,557,000 (\$0.03 net loss per share) as compared to a net loss of \$8,571,000 (\$0.03 net loss per share) for the year ended September 30, 2020.

The net loss was higher during the year ended September 30, 2021 mainly due to higher R&D costs that were approximately \$3,004,000 higher year-over-year. Approximately \$2,200,000 of the increase was due to increased scope of R&D, clinical & regulatory work. The cost of the hiring of certain consultants to the Company that supported FDA and Health Canada regulatory submissions during the fiscal year ended September 30, 2021 totalled \$702,000. An additional \$575,000 was spent on critical supplies that supported the Company's research and development work and \$473,000 was spent on clinical studies in partnership with the University of Buffalo. The remainder of the costs was spent on several activities to help support the commercial launch of new testing products.

Additionally, R&D expenses increased during fiscal 2021 due to higher compensation (\$501,000) expenses to support growth and higher costs related to lab and clinical supplies (\$303,000).

## **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: the infrastructure development for a US sales network, our clinical development and research activities and the regulatory decisions by the NYSDOH and Health Canada.

Operating activities for the quarter ended September 30, 2021 were financed by cash on hand.

As of September 30, 2021, current assets were \$3,638,000 including \$2,295,000 of cash compared to 3,668,000 of current assets that included \$2,596,000 of cash as of September 30, 2020. As of September 30, 2021, the Company had a \$686,000 working capital surplus compared to a surplus of \$2,203,000 as of September 30, 2020.

Cash used in investing activities for the year ended September 30, 2021, was \$1,609,000 as compared to \$182,000 for the year ended September 30, 2020. Cash used in investing activities was spent to increase the manufacturing capacity by adding more equipment and leasehold improvements to increase the manufacturing footprint.

The Company has a principal amount of approximately \$2.5 million in long-term debentures with an interest rate of 10% and maturity of approximately four years.

### **Subsequent to the Quarter**

#### *Private Placement*

In November 2021, the company has completed a non-brokered private placement of an aggregate of 26,932,895 units of the Company's at a price of \$0.19 per unit for gross proceeds of approximately \$5,100,000. 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. The net proceeds of the private placement were used to fund the Company's product commercialization and manufacturing programs, including the Company's submission to the NYSDOH for the EXACT COVID-19 Antibody Test, sales and marketing and for general working capital purposes.

#### *RALI-Dx™ IL-6 Severity Triage Test submission to Health Canada*

The Company completed its submission for an Interim Order to Health Canada for its RALI-Dx™ IL-6 Severity Triage Test in the first quarter of fiscal 2022. Management believes that an approval by Health Canada would be a significant milestone for the Company, as the RALI-Dx™ IL-6 Severity Triage Test would be the first of its kind to enter the Canadian market.

#### *Filed provisional patent for microarray image analysis*

In the first quarter of fiscal 2022, the Company filed a provisional patent for the analysis of microarray images through the detection of biological protein markers in a biological matrix, in particular the analysis of positional microarray images of multiplex immunoassay detection zones.

### *Acquisition of assets from Precision Biomonitoring Inc.*

On January 10, 2022, the Company announced the signing of a definitive agreement to acquire, through its wholly owned subsidiary, SQI Diagnostics Systems Inc., substantially all the assets underlying Precision Biomonitoring Inc.'s human diagnostics COVID-19 PCR testing business and its TripleLock molecular diagnostic testing technology for aggregate cash and share consideration of \$6,825,000 (the "**PBI Acquisition**"). Completion of the PBI Acquisition is subject to customary conditions including, but not limited to, the completion of satisfactory due diligence and the approval of the TSX Venture Exchange Inc. Closing of the PBI Acquisition is anticipated on or before February 14, 2022.

### *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 389,463,134 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:

<b>Number of Warrants (000s)</b>	<b>Exercise Price</b>	<b>Maturity</b>
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
<b>144,049</b>		

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	3.09 years
23,798	\$ 0.15 - 0.22	3.78 years
1,455	\$ 0.23 - 0.30	8.59 years
26,625		

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 audited financial statements for the year ended September 30, 2021. Refer to the audited financial statements for the year ended September 30, 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**

##### ***Uncertain Future Capital Needs and Additional Financing***

SQI has used the proceeds from its previous equity offerings, and intends to use the proceeds from any possible future offerings, to, among other uses, continue to develop novel IVD products, finalize the development of the products currently in its pipeline including the EXACT COVID-19 Antibody Test, the RALI-Dx™ and the RALI-fast™ Point-of-Care (POC) tests, file patent applications to protect these IVD Products and related intellectual property and advance its existing IVD Device portfolio through regulatory approval, all of which will require substantial additional capital. Because

of the uncertainty surrounding the successful development of viable IVD products, SQI is unable to estimate the actual amount of funding it will require to complete such activities. The amount and timing of SQI's future funding requirements will depend on many factors, including but not limited to:

- whether SQI is successful in obtaining the benefits of Health Canada's and the FDAs expedited emergency use authorization review programs related to its IVD Products;
  - the progress, costs, results of and timing of product prototype testing;
  - the outcome, costs and timing of seeking and obtaining Health Canada, FDA, NYSDOH (for the EXACT COVID-19 Antibody test) and any other regulatory approvals that may be required.
  - the costs associated with securing and establishing commercialization and manufacturing capabilities;
  - market acceptance and adoption rate of its IVD Products;
  - the costs of acquiring, licensing or investing in businesses and products and technologies;
  - its ability to maintain, expand and enforce the scope of its intellectual property portfolio, including the amount and timing of any payments the Company may be required to make, or that it may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;
  - its need and ability to hire and retain additional management and scientific personnel;
  - the effect of competing IVD products;
  - its need to implement additional internal systems and infrastructure, including financial and reporting systems;
  - changes in the political and economic environment in the jurisdictions in which SQI operates, including adverse economic circumstances beyond COVID-19;
- the duration and effects of COVID-19 on SQI's personnel, business, operations and financial condition;
- the duration and effects of COVID-19 (and other chronic and infectious diseases) on the global population and the corresponding need for testing products;
  - unforeseen and unanticipated design flaws of the Company's products resulting in ineffective or inaccurate testing results; and

- the economic and other terms, timing of and success of any collaboration, licensing or other transactions into which SQI may enter in the future.

Some of these factors are outside of SQI's control. SQI does not believe that its existing capital resources are sufficient to enable it to complete the development and commercialization of its IVD products. Accordingly, SQI expects that it will need to raise additional funds in the future. SQI may seek additional funding through a combination of equity offerings, debt financings, government or other third-party funding, commercialization, marketing and distribution transactions and other collaborations, strategic alliances and licensing transactions. Additional funding may not be available to SQI on acceptable terms or at all. In addition, the terms of any financing may adversely affect the holdings or the rights of SQI securityholders. In addition, the issuance of additional Common Shares, or the possibility of such issuance, may cause the market price of the Common Shares to decline. Any additional equity financing may be dilutive to investors and debt financing, if available, may involve restrictions on financing and operating activities. If SQI is unable to obtain funding on a timely basis, it may be required to significantly curtail one or more of its research or development programs. SQI also could be required to seek funds through transactions with collaborative partners or otherwise that may require SQI to relinquish rights to some of its intellectual property or otherwise agree to terms unfavourable to SQI.

### ***History of Losses***

We have limited commercial history and have incurred significant losses in each fiscal year since inception. As of September 30, 2021, we had an accumulated deficit of \$114 million. These losses have resulted principally from costs incurred in our research and development programs and from our sales, general and administrative expenses. Because of the numerous risks and uncertainties associated with our commercialization efforts and future product development, there is risk associated with the timing of achieving profitability, and we may never become profitable.

### ***Market Competition***

The markets for our products are characterized by rapidly changing technology, evolving industry standards, changes in customer needs, emerging competition, new product introductions and strong price competition. We compete with both established and development-stage companies, universities, research institutions, governmental agencies and healthcare providers that design, manufacture and market similar diagnostic products, many of whom have significantly greater financial and human resources, research, development and marketing capabilities, intellectual property and name recognition than the Company. The Company's competitors may succeed in developing technologies and products that are more effective than any products developed by the Company, or that would render the Company's technology and products obsolete.

We anticipate that we will face increased competition in the future as existing companies and competitors develop new or improved products and as new companies enter the market with new technologies, which is likely to result in pricing pressures, which could harm our sales, profitability or market share. Our failure to compete effectively could materially and adversely affect our business, financial condition and operating results.

### ***Market Acceptance of Products***

Our success depends, in part, upon our ability to develop and market products that are recognized and accepted as reliable, accurate, timely and cost effective by physicians, lab technicians and administrators. Most of our potential customers already use expensive diagnostic products and systems in their laboratories and may be reluctant to replace those systems. Market acceptance of our products and technologies will depend upon many factors, including our ability to provide a broad menu of tests to potential customers, and our ability to convince potential customers that our systems are an attractive cost- and time-saving alternative to existing technologies. Compared to most competing technologies, our microarray assay technology is relatively new, and most potential customers have limited knowledge of, or experience with, our products. Prior to adopting our microarray assay technology, some potential customers may need to devote time and effort to testing and validating our systems. Any failure of our systems to meet these customer benchmarks could result in customers choosing to retain their existing systems or to purchase systems other than ours.

### ***Product Recalls and Liability Claims***

If the Company's products produce inaccurate or inconsistent results, do not function as designed, are inappropriately designed or are not properly produced, the Company may have to withdraw such products from the market and/or be subject to product liability claims. Although the Company expects to maintain insurance against product liability and defense costs in amounts believed to be reasonable, there is no assurance that the Company can successfully defend any such claims or that the insurance it expects to carry will be sufficient. A successful claim against the Company in excess of insurance coverage could have a material adverse impact on its business, financial condition and results of operations.

### ***Complex Regulatory Compliance Requirements***

We operate in a highly regulated industry and we are subject to the authority of certain regulatory agencies, including Health Canada, Centers for Medicare & Medicaid Services (CMS) and the FDA. As we enter new markets (e.g., Europe), we may become subject to additional regulatory requirements from applicable health authorities. These requirements encompass the design, development, testing, supply chain management, manufacturing, marketing and sale of our diagnostic products. Failure to maintain regulatory certification of our quality system or failure of our manufacturing facilities to meet regulatory standards could materially affect our ability to manufacture or market our products successfully and could therefore have a material adverse effect on our business.

The Company will be required to hold a variety of permits and licenses to comply with operational and security standards of the various governmental agencies. Any failure to adhere to these standards, or maintain appropriate permits, could disrupt Company operations and adversely affect the Company's results. Part of the Company's growing operations may involve collecting and maintaining patient-identifying information or other sensitive personal and financial data, which is subject to a variety of federal, provincial and foreign laws that regulate the use and disclosure of such information. Regulations currently in place continue to evolve, and new laws in this area could further restrict the Company's ability to collect, handle and maintain personal or patient information, or could

require the Company to incur additional compliance costs, either of which could have an adverse impact on the Company's results of operations. Violations of federal, provincial or foreign laws concerning privacy and data protection could subject the Company to civil or criminal penalties, breach of contract claims, costs for remediation and harm to the Company's reputation.

Additionally, the authority of the regulatory agencies or the application of certain regulations may be expanded or otherwise changed in such a manner that would place additional regulatory burdens on us or our customers. Such a change in our industry could have a material adverse effect on our business.

### ***Rapidly Changing Technology and Customer Requirements***

The field of diagnostics is characterized by rapidly changing and developing technologies that include new products that could render our diagnostic processing equipment and consumable tests obsolete at any time, and thereby adversely affect our financial condition and future prospects. Our success depends upon our ability to anticipate changes in technology and customer requirements and develop new products with improved performance and cost effectiveness in existing and new markets.

Developing and marketing new products and services will require us to incur substantial development costs, and we may not have adequate resources available to be able to successfully introduce new versions of, or enhancements to, our products. While we plan to continue to make improvements to our diagnostic processing equipment and consumable tests, we may not be able to successfully implement these improvements. Even if we successfully implement some or all these improvements, we cannot guarantee that potential customers will find our enhanced products to be an attractive alternative to existing technologies, including our current products.

### ***Research and Development Activities***

New diagnostic products, and improvements to existing diagnostic products, require significant research, development, testing and investment prior to any final commercialization. Our business depends on the continued development and improvement of our existing products, our development of new products to serve existing markets and our development of new products to create new markets and applications that were previously not practical with existing systems. We believe that the adoption of our platform by potential customers depends, in part, upon our ability to provide a broad menu of tests to potential customers.

We intend to devote significant personnel and financial resources to research and development activities designed to advance the capabilities of our diagnostic technology and, in the case of our In vitro Diagnostics ("IVD") business, to obtain regulatory approval of additional tests. In the past, our product development projects have been delayed. We may have similar delays in the future, and we may not obtain any benefits from our research and development activities. Any delay or failure by us to develop new products, to receive applicable regulatory clearances or approvals, produce the products in commercial quantities at reasonable costs, successfully market the products, or to enhance existing products would have a material adverse effect on our business and results of operations.



Our long-term success must be considered in light of the expenses, difficulties and delays frequently encountered in connection with the development of new technology and the competitive and highly regulated environment in which we operate.

### ***Marketing and Distribution***

We are in the early stages of commercializing, selling, distributing, and marketing of products, in which we have limited experience. We intend to market, sell and distribute our products directly through our own sales force in North America, Europe and elsewhere. Our future sales will depend in large part on our ability to develop and substantially expand our direct sales force and to increase the scope of our marketing efforts.

Our products are technically complex and used for specialized applications. As a result, we believe it is necessary to develop a direct sales force that includes people with specific scientific backgrounds and expertise and a marketing group with technical sophistication. Competition for such employees is intense. We may not be able to attract and retain personnel or be able to build an efficient and effective sales and marketing force, which could negatively impact sales of our products, and reduce any future revenues and profitability.

If our sales, marketing, and distribution efforts are not successful, our technologies and products may not gain market acceptance, which would materially impact our business operations.

### ***Reliance on Key Suppliers***

We rely on key suppliers for certain components and materials used in our platform technologies, including our sqidlite and sqid-X diagnostic platforms and our microarrays. We do not have agreements with these key suppliers to supply us with components in the future. The loss of any of these key suppliers would require significant time and effort to locate and qualify an alternative source of supply. There are a limited number of suppliers who can manufacture the highly specialized equipment that forms a part of our systems. In addition, any change in any component that forms a part of our systems will require additional testing to ensure that it performs in a substantially similar manner to the existing component. Any interruption or delay in the supply of components or materials, or our inability to obtain components or materials from alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand of our strategic partners and future customers.

### ***Legislative or Regulatory Change***

The healthcare regulatory environments in the jurisdictions in which we operate and plan to operate may change in a way that restricts our ability to market our diagnostic testing products. In some situations, sales of our diagnostic systems will depend, in part, upon the extent to which the costs to patients of such tests are paid by health maintenance, managed care, and similar healthcare management organizations, or reimbursed by government health payor administration authorities, private health coverage insurers and other third-party payors. The Company expects the healthcare and IVD industry to continue to change significantly and these potential changes, which may include a reduction in government support of healthcare services, adverse changes in legislation or

regulations, and further reductions in healthcare reimbursement practices, could have a material adverse effect on the Company's business, results of operations and financial condition.

### ***Key Personnel***

The Company's management team consists of a core group of experienced senior executive officers. The loss of the technical knowledge, management expertise, and knowledge of the Company's and its clients' operations of one or more members of the Company team could result in a diversion of management resources, as the remaining members of management would need to cover the duties of any senior executive who leaves the Company and would need to spend time usually reserved for managing its business to search for, hire and train new members of management. Additionally, as members of the Company's management team have built strong relationships in the healthcare sector, the loss of these relationship contacts could have an adverse effect on the Company's business. The Company does not expect to carry "key man" insurance that could compensate it for the loss of any of its senior executives. The loss of some or all of the Company's management team or other key personnel, particularly those personnel with clinical, regulatory, and R&D experience, could negatively affect the Company's ability to develop and pursue the Company's growth strategy, which could adversely affect the Company's business and financial condition. Any departures of key personnel could also be viewed in a negative light by investors and analysts, which could cause the market price of the Common Shares to decline. Additionally, the market for key personnel in the industry in which the Company will compete is highly competitive and not concentrated in all of the locations in which it expects to operate. As a result, the Company may not be able to attract and retain key personnel with the skills and expertise necessary to manage its business and pursue its growth strategy.

### ***Development or Manufacturing Delays***

We have been developing our core technologies in our facilities in Toronto, Canada, which we believe has adequate space to expand the manufacturing capacity to our expected needs for the foreseeable future. However, we may encounter unforeseen situations at this facility that may result in delays or shortfalls in our development and production. In addition, our development and production processes and assembly methods may have to change to accommodate any significant future expansion of our manufacturing capacity. If we are unable to keep up with the development of or demand for our products, our revenue could be impaired, market acceptance for our products could be adversely affected and our customers might instead purchase our competitors' products. Our inability to successfully manufacture our products would have a material adverse effect on our business, financial condition and results of operations.

### ***Unknown Defects or Errors***

Our products utilize complex technologies applied on a small scale, and our systems may develop or contain undetected defects or errors. As our production levels increase, material performance problems, defects or errors could arise. The costs incurred in correcting any defects or errors may be substantial and could adversely affect our operating margins.

In manufacturing our products, we depend upon third parties for the supply of various components. Many of these components require a significant degree of technical expertise to produce. If our

suppliers fail to produce components to specification, or if defective materials or workmanship are used in the manufacturing process, the reliability and performance of our products will be compromised. The occurrence of any one or more of the foregoing could negatively affect our business, financial condition and results of operations.

### ***Foreign Exchange Fluctuations***

We expect that a significant portion of our future revenues and expenses will be denominated in U.S. currency, and, therefore, we will be subject to fluctuations in exchange rates. There is a risk that significant fluctuations in exchange rates would negatively affect our operating margins and would therefore have an adverse effect on our future results of operations.

### **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, a novel strain of coronavirus (“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 Common Shares 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 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 Common Shares.

### ***Impact of COVID-19 on Our Results***

During the year, 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 September 30, 2021, the Company participated in the Canada Employment Wage Subsidy and Biotalent Student Work Placement program, where payments of \$376,000 and \$32,000 were received under these programs respectively to partially offset employee wages during the period. For the year ended September 30, 2021 payments of \$1,085,000 and \$73,000 were received from the Canada Employment Wage Subsidy and Biotalent Student Work Placement program, respectively. Amounts received are grants from the federal government and are not expected to be repaid.

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

The Company has a number of new products currently 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 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 be in excess of 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

### **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 September 30, 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 September 30, 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

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

**R&D:** Research and development

**sqidlite™:** Our bench-top diagnostic system – fully automated bench top microarray processing system

**sqid-X™:** **sqid-X™** System – semi-automated bench-top platform that incorporates all of SQI's technology with the exception of automated fluidics handling

**PCR:** Polymerase Chain Reaction

**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