



**SQI DIAGNOSTICS INC.**

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

**September 30, 2022**

## **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, 2022 and 2021. The annual audited financial statements and MD&A for the year ended September 30, 2022 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 30, 2023.*

*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 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;*
- *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. We develop and manufacture respiratory health and precision medicine tests that run on SQI’s fully automated systems. Our tests have been developed for Rapid Acute Lung Injury testing, donor organ transplant informatics and immunological protein and antibody testing, and to simplify the diagnostic testing process, including with respect to COVID-19 antibody monitoring. 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 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

received approval for an Interim Order from Health Canada for RALI-Dx™ IL-6 Severity Triage Test subsequent to the fourth quarter of fiscal year 2022 and currently expects to apply for an Interim Order for RALI-fast™ in fiscal year 2023.

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 we will scale up our development for other significant transplant market opportunities in the kidney and live transplant sectors.

SQI's clinical research partner at University Health Network (UHN), is leading force in the 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. 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. UHN is considered a world leader in the lung transplant business and our TORdx™ LUNG Test a key piece of this new solution.

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.

## **Existing Products and Services**

### Exact Antibody Test

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 filed with the New York State Department of Health ("NYSDOH") for approval of the use of the EXACT COVID-19 Antibody Test and collection kit and received approval in the second quarter of fiscal year 2022. The test is now available as a direct-to-consumer product which allows people to avoid travelling to a clinic or hospital to be tested for the presence of the SARS-COV-2 antibodies.

The EXACT Antibody test is meant to be a serial test where consumers with an interest in their COVID-19 antibody levels can test themselves over a period of time. The EXACT COVID-19 Antibody Test provides semi-quantitative measurements of six distinct antibodies produced by the immune system in response to exposure to the SARS CoV-2 virus or to COVID-19 vaccination. The Company intends to pursue the marketing and sale of this test using directly and through partnerships including targeting pharmacies in the United States; however, there can be no assurance as to when such sales may commence, if at all. The Company also recently hired a salesperson in the United States, whose responsibility is to pursue sales with large employers and other potential purchasers of the test.

### Direct-to-Consumer Tests

This segment represents commercial-ready autoimmune tests that are sold to 3<sup>rd</sup> parties who obtain samples that are tested on our kits. These tests have been approved for use and are a continual source of revenue for the

Company. These tests are sold online through the Company's distribution partner, Immaware, in the United States. Typical customers include those interested in testing themselves for diseases such as Celiac or RA. The Company receives revenue based on the number of tests sold.

### Distribution Testing Business

As a result of the PBI Acquisition, the Company is now a distributor of PCR and Antigen tests for COVID-19 disease. The PCR tests are sold to businesses to conduct on-site employee screening. The antigen tests are being sold to businesses in a similar capacity as the PCR tests and also to employers looking to screen their employees before they return to the office. The Company employs in-house salespeople who are responsible for covering the Canadian market. Customers include companies in sectors such as mining, moving production, food and beverage and other industries where tests are either mandated by unions or where companies understand the benefits of service disruption to their business and utilize testing as a preventative measure.

### **Business Strategy**

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, organ transplant, COVID-19 testing and autoimmune disease. We believe the consumer market wants access to convenient, accurate rapid diagnostic healthcare tests. The organ transplant business represents a growing opportunity for the Company. Our development and marketing strategy includes:

- Successful clinical development completion and regulatory approval of our diagnostic products
- Establish clinical partnerships in the U.S. to support future FDA filing of our TORdx LUNG™ organ assessment assay
- Successful marketing and sales of our DTC and B2B diagnostic tests via strategic business partnerships
- Expansion of our commercial testing operations in the U.S. via partner labs
- Acquisition of key talent to build our business
- Potential in-licensing and out-licensing of technologies and products such as our 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.

## Financial Highlights for the Quarter

Revenues increased to \$1,202,000 during the Company's fourth quarter of fiscal 2022 compared to \$143,000 during the same quarter in the previous year. The increase in revenue is attributable primarily to the PCR testing business which the Company acquired in the second quarter of fiscal 2022. PCR testing revenue accounted for \$921,000 or approximately 77% of total revenues. During the quarter, the Company also recognized the remaining portion of deferred revenue relating to projects based on its partnership with the UHN.

Corporate & General expenses during the Company's fourth quarter of fiscal 2022 of \$382,000 were lower as compared to the previous year's quarter \$874,000. The decrease was mainly a result of a credit of \$316,000 due to the re-allocation of financing fees to interest expense and a credit of \$234,000 in stock-based compensation as a result of an expense reversal for certain milestone options partially offset by higher salaries & wages of \$228,000, reflecting a full quarter of the CEO compensation in the current quarter versus one month in the corresponding quarter prior year as well as a re-allocation of a portion of the CSO's compensation costs from R&D to Corporate & General in addition to higher professional fees of approximately \$130,000 primarily related to audit, legal and investor relations.

## SELECTED FINANCIAL INFORMATION

### Quarterly Metrics and Analysis

The table below summarizes quarterly financial information for the three months and twelve months ended September 30, 2022.

	Three months ended September 30, 2022 (000s)	Three months ended September 30, 2021 (000s)	Twelve months ended September 30, 2022 (000s)	Twelve months ended September 30, 2021 (000s)
Revenue	\$1,202	\$143	\$8,102	\$917
Net Loss	\$(7,848)	\$(2,600)	\$(18,523)	\$(10,557)
Net Loss per share	\$(0.02)	\$(0.01)	\$(0.05)	\$(0.03)
Weighted Average Shares	393,635	338,454	389,720	338,454

## Revenues

During the three-month and twelve-month period ended September 30, 2022, the Company recorded revenue from the sale of COVID-19 PCR testing kits, custom kits, as well as service revenue to our diagnostic customers. The table below summarizes revenue by category.

	Three months ended September 30, 2022 (000s)	Three months ended September 30, 2021 (000s)	Twelve months ended September 30, 2022 (000s)	Twelve months ended September 30, 2021 (000s)
Product Sales - COVID-19 PCR Kits	\$921	-	\$7,564	-
Product Sales - Kits	\$82	\$70	\$203	\$462
Service Revenue	\$199	\$73	\$335	\$455
Total Revenues	\$1,202	\$143	\$8,102	\$917

*Three months:*

### Product Sales – PCR Kits

The Company generated PCR testing revenue of \$921,000 in the fourth quarter of 2022 compared to nil in the fourth quarter of 2021 as the business was acquired in the second quarter of 2022.

### Product Sales – Kits

Product sales were slightly higher in the fourth quarter of 2022 compared to product sales in the same period in 2021 as the Company recognized the remaining amount in deferred revenue pertaining to two agreements the Company had entered with the UHN: the RALI-Dx™ IL-6 Severity Triage Test and a project funded by a previously announced CIHR Grant. This higher revenue was somewhat offset by lower revenue from the sale of Celiac kits.

### Service Revenue

Service revenues were higher in the fourth quarter of 2022 compared to the same period in 2021 primarily due to the recognition of \$155,000 in revenue associated with R&D work for assay development for the UHN; the Company recognized this revenue due to a mutually agreement between both parties as the cost to complete this project was in excess of the revenue generated and no further work was deemed necessary.

*Twelve months:*

### Product Sales – Kits

The Company generated PCR testing revenues of \$7,564,000 in fiscal 2022 compared to nil in fiscal 2021 as the business was acquired in the second quarter of 2022. PCR testing revenues were not related to travel testing, which are more volatile based on travel restrictions but were instead made to businesses who were keen on testing their employees for COVID-19. Some businesses in the TV and Film industries are subjected to union mandated testing so despite the ease of COVID-19 restrictions by various governments and companies, the Company continued to experience success in its PCR testing business albeit at lower levels compared to previous months.

### Service Revenue

Service revenues in fiscal 2022 were \$335,000 as compared to \$455,000 in fiscal 2021. The decrease in year-over-year service revenues was a result of nil sales in the Life Sciences sector, which the company exited in 2021 compared to sales of \$126,000 in 2020. The Company exited the Life Science segment of its business in 2021 to focus on its core projects in respiratory health, where the margins are more attractive and addressable markets are larger, in an effort to accelerate its regulatory filings. The Company also generated lower service revenues from two of its customers due to lower business activity and its decision to cease business with one of its customers. The reduction in services revenues as mentioned above was partially offset by higher service revenues from the Company's R&D project with the UHN.

## **Net Loss**

### *Three months:*

For the quarter ended September 30, 2022, the Company recorded a net loss of \$7,848,000 (\$0.02 net loss per share) as compared to a net loss of \$2,600,000 (\$0.01 net loss per share) in the quarter ended September 30, 2021.

The net loss was higher in the fourth quarter of 2022 compared to the corresponding quarter in the previous year mainly due to higher costs in several areas including interest of \$1,682,000, amortization of intangible assets of \$1,449,000, impairment loss associated with assets acquired in the PCR Business of \$2,873,000, COGS of \$1,513,000. These higher costs were partially offset by higher sales of \$1,059,000, lower Corporate & General expenses of \$492,000 and lower R&D expenses of \$173,000 and a gain of debt modification of \$1,037,000. As mentioned previously, higher sales were generated by the PCR testing business. As a result of this acquisition of assets, the Company utilized a credit of facility of \$7.5 million, resulting in higher interest expense in the current period. The intangible assets acquired resulted in significantly higher amortization costs and during the quarter the Company reassessed its forecast for COVID-19 testing revenue and consequently booked an impairment loss based on the economic outlook and governments as well as businesses' shift in their stance pertaining to COVID-19 testing. The gain on debt modification is an accounting transaction that essentially revalues the Pivot Credit facility at each extension date.

### *Twelve Months:*

For the year ended September 30, 2022, the Company recorded a net loss of \$18,523,000 (\$0.05 net loss per share) as compared to a net loss of \$10,557,000 (\$0.03 net loss per share) for the year ended September 30, 2021.

The net loss was higher in fiscal 2022 compared to the loss in fiscal 2021 mainly due to higher costs in several areas including interest of \$2,082,000, amortization of intangible assets of \$2,994,000, impairment loss associated with the assets acquired in the PCR Business of \$2,873,000, COGS of \$4,849,000, and Corporate & General of \$3,376,000. These higher costs were partially offset by higher sales of \$7,185,00 and a gain on debt modification of \$1,037,000. As mentioned previously, higher sales were generated by the PCR testing business. As a result of this acquisition of assets, the Company utilized a credit of facility of \$7.5 million, resulting in higher interest expense in the current year. The intangible assets acquired resulted in significantly higher amortization costs and at the end of the fiscal year, the Company reassessed its forecast for COVID-19 testing revenue and consequently booked an impairment loss. Interest expense was also higher during the year as the Company increased its outstanding debt in June 2022 by \$4.05 million. Corporate & General expenses increased in fiscal 2022 compared to fiscal 2021 due to higher salaries & wages including lower CEWS in 2022, the absence of any bad debt recovery compared to a recovery of \$407,000 in the previous year, transition support costs associated with the PBI



acquisition, higher professional fees primarily related to investor relations, legal and recruiting, and higher software subscription costs to support the increasing complexity of the business.

## **Liquidity and Balance Sheet**

Management expects further investments in our planned 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 as it transitions from an R&D organization to a commercial one.

The Company continues to seek ways of obtaining capital to operate and execute its business plan and are consistently engaging with investment bankers and other intermediaries to assist with funding. In the absence of external funding the Company's three controlling shareholders and current Board members who collectively owns about 76% of the outstanding shares have historically funded the business, however, there are no assurances that these shareholders will continue to provide funding. Factors that will affect our future anticipated cash requirements include but are not limited to the following: the pace of our clinical development and research activities for its keystone products as well as the amount of margins generated by the COVID-19 testing business to help defray operating costs.

Operating activities for the quarter ended September 30, 2022 were financed by cash raised through a debenture offering in June 2022 and also by cash generated from the PCR testing business.

As of September 30, 2022, current assets were \$3,276,000 including \$1,336,000 of cash compared to \$3,638,000 of current assets that included \$2,295,000 of cash as of September 30, 2021. As of September 30, 2022, the Company had a 7,428,000 working capital deficit compared to a surplus of \$686,000 as of September 30, 2021.

Cash used in investing activities for the year ended September 30, 2021, was \$7,500,000 as compared to \$1,609,000 for the year ended September 30, 2021. In fiscal 2022, cash used in investing activities was spent to acquire the PBI assets and to also acquire manufacturing equipment designed to increase throughput while cash used in investing activities in 2021 was spent to increase manufacturing capacity by adding more equipment and on 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 three years, a principal amount of \$4.05 million in long-term debentures with an interest rate of 8% and maturity of approximately four years and a \$7.5 million credit facility that comes due on January 31, 2023. On January 30, 2023, Pivot Financial extended the Maturity date to February 3, 2023 with the intent of having discussions with Management about a potential further extension.

## **Subsequent to the Quarter**

### *Signed interest free loan agreement with FedDev Ontario*

On November 10, 2022, The Company entered into a funding agreement (the "Contribution Agreement") with the Federal Economic Development Agency for Southern Ontario ("FedDev Ontario") to support the Company's manufacturing scale-up and commercialization of its pipeline of products in development. Under the terms of the Contribution Agreement, the Company will be able to draw down up to \$2 million of funding in the form of interest-free contributions. The loan is repayable over five years once repayment commences in 2024. As of the printing of this MD&A, the Company has drawn approximately \$1.7 million on this loan.

### *Extension of Pivot Credit Facility and Deferral of Certain Interest Payments*

On October 19, 2022, the Pivot Credit Facility was extended to January 31<sup>st</sup>, 2023, from October 28<sup>th</sup>, 2022. The Insiders and controlling shareholders of SQI, who are parties to the Pivot Credit Facility also agreed to temporarily defer their portion (50% of the total of \$7.5 million) of the interest payments. The Company paid an amended fee of \$37,500 plus HST and the Lenders counsel's legal fee of \$5,171. The Credit Facility is not convertible into any securities of the Company. Additionally, the holders of the \$4.05 million principal debentures dated June 17<sup>th</sup>, 2022, which are controlled by certain insiders of the Company who are also control persons of the Company, have agreed to the temporary deferral of interest payments under the Debentures together with the Pivot Interest Deferral. All other terms of the Credit Agreement remain unchanged. On January 30, 2023, Pivot Financial extended the Maturity date to February 3, 2023 with the intent of having discussions with Management about a potential further extension.

### *Private Placement*

In December 2022, the company has completed a non-brokered private placement of an aggregate of 12,611,112 units of the Company's at a price of \$0.09 per unit for gross proceeds of approximately \$1,135,000. 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 \$0.12 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.

### *RALI-Dx™ IL-6 Severity Triage Test approval by Health Canada*

The Company secured an Interim Order from Health Canada for its RALI-Dx™ IL-6 Severity Triage Test in November 2022. The RALI-Dx™ IL-6 Severity Triage Test is the first of its kind to enter the Canadian market.

### **Outstanding Capital Stock**

As of the date of this MD&A, there were 406,246,025 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</b>	<b>Exercise Price</b>	<b>Maturity</b>
26,018	\$0.20	December 20, 2022 – August 24, 2023
12,344	\$0.17	July 12, 2024
32,300	\$0.13	September 25, 2024 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 to November 8, 2026
<b>142,661</b>		

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

<b>Number of Options</b>	<b>Range of Exercise Prices</b>	<b>Weighted average time to maturity</b>
4,223	\$ 0.07 – 0.14	4.12 years
23,927	\$ 0.15 – 0.22	3.23 years
1,265	\$ 0.23 – 0.30	7.91 years
29,415		

Some options granted to Mr. Andrew Morris, CEO, and Mr. Eric Brouwer, CSO, which are included in the table above are performance-based. These options 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, 2022. Refer to the audited financial statements for the year ended September 30, 2022 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 Diagnostic products, finalize the development of the products currently in its pipeline the RALI-fast™ Point-of-Care (POC) test, file patent applications to protect these Diagnostic Products and related intellectual property and advance its existing Diagnostics Device portfolio through regulatory approval, all of which will require substantial additional capital. Because of the uncertainty surrounding the successful development of viable Diagnostic 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:

- the progress, costs, results of and timing of product prototype testing;
- the costs associated with securing and establishing commercialization and manufacturing capabilities;

- market acceptance and adoption rate of its Diagnostic 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 Diagnostic 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 Diagnostic 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, development or clinical 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, 2022, we had an accumulated deficit of \$132 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 Diagnostic 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 primarily 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 Diagnostic 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.

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. 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 quarter ended September 30, 2022, the Company participated in the Canada Employment Wage Subsidy and Biotalent Student Work Placement program, where payments of nil and nil were received under these programs respectively to partially offset employee wages during the period. For the year ended September 30, 2022 payments of \$177,000 and \$60,000 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.

## **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 Diagnostic 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 Diagnostic 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 Diagnostic 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, 2022;

(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, 2022; 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