

# SQI DIAGNOSTICS INC.

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

September 30, 2020

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

This Management's Discussion and Analysis ("MD&A") covers the interim financial statements for the years ended September 30, 2020 and 2019. The annual audited financial statements and MD&A for the year ended September 30, 2020 and the most recent Annual Information form ("AIF") can be found on SEDAR at www.sedar.com.

All amounts are expressed in Canadian dollars unless otherwise indicated.

This discussion and analysis was prepared by management using information available as of January 27, 2021.

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;
- 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; and
- volatility of share price and an active market for our shares.
- 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 Diagnostics, Inc. is a precision medicine company that discovers, develops, and commercializes innovative rapid diagnostic testing for healthcare providers, patients, and consumers worldwide. The Company's proprietary advanced diagnostics target organ transplant, autoimmune disease and COVID-19 testing which include the developmental direct-to-consumer COVID-19 HOME Antibody Test, the RALI-dx<sup>TM</sup> COVID-19 Severity Triage Test and the COVID-19 RALI-fast<sup>TM</sup> Severity Triage Point-of-Care (POC) Test. SQI's rapid diagnostic tests are intended to be sold to healthcare professionals so that patients can get accurate results and fast effective treatment, and direct-to-consumer SQI is fast-tracking the development of three COVID-19 diagnostic tests: a direct-to-consumer COVID-19 Antibody Test and two COVID-19 Severity Triage tests. The COVID-19 HOME Antibody Test identifies the presence of IgM, IgA and IgG antibodies of SARS-CoV-2 in individuals suspected to have been infected with COVID-

19 and asymptomatic individuals wanting to know if they have been exposed. The test is > 99% accurate with results delivered in 24-48 hours. The Company currently expects to apply to the U.S. Food and Drug Administration ("FDA") for Emergency Use Authorization ("EUA") for its COVID-19 HOME Antibody Test in the second quarter of calendar year 2021. Should the COVID-19 HOME Antibody Test receive regulatory approval, the test is expected to be available direct-to-consumer which would allow individuals to avoid travelling to a clinic or hospital to be tested for the presence of the SARS-CoV-2 antibody.

The RALI-dx<sup>TM</sup> COVID-19 Severity Triage Test and the RALI-fast<sup>TM</sup> COVID-19 Severity Triage POC Test each help clinicians identify which patients with SARS-CoV-2 will have a severe inflammatory response and should be admitted to the hospital or not. Both tests measure the critical biomarker IL-6 which plays a key role in the cytokine storm phase of COVID-19. The RALI-dx<sup>TM</sup> delivers results from the lab in about 50 minutes while the RALI-fast<sup>TM</sup> delivers results at the patient point-of-care in about 15 minutes. The Company currently expects to apply for EUA to the FDA and for an Interim Order with Health Canada for both tests in the first and second quarters of calendar year 2021, respectively.

Under organ transplant, SQI is pioneering the development of an advanced diagnostic test that increases the chance of successful lung transplant by assessing the health of the donor organ prior to transplant surgery. The Company's developmental TORdx<sup>TM</sup> Lung Test can detect inflammation at the molecular level to assess the health of the donor lung, enabling surgeons to transplant healthy lungs which otherwise would have been rejected; there is currently no other such test. SQI has partnered clinical development with the University Health Network (UHN) Hospitals, one of the largest health and medical research organizations in North America. Upon regulatory approval of the TORdx<sup>TM</sup> Lung Test, clinical development is planned for diagnostic tests designed to increase the chance of successful kidney and liver transplant.

The TOR $dx^{\text{TM}}$  LUNG Test is a breakthrough diagnostic that is expected to significantly increase the number of lung transplants for patients in the U.S. and Canada. SQI is working with U.S. and Canadian regulatory agencies to obtain regulatory approval, however submission reviews have been suspended as a result of the COVID-19 pandemic.

We intend to initiate clinical development on similar, diagnostic tests designed to increase the chance of successful kidney and the liver transplants upon receipt of regulatory approval of the TOR $dx^{\text{TM}}$  LUNG Test.

In fiscal 2020, SQI began clinical development on additional lung transplant diagnostics to help surgeons determine the health of the organ prior to transplant surgery and increase organ availability and the chance of successful lung transplant:

1. A quantitative test that enables the monitoring and guidance of therapeutic treatments of the donor lung while on Ex Vivo Lung Perfusion ("EVLP"). This test is designed to broaden the capabilities of organ repair to include the therapeutic

treatment of infection and other causes of poor recipient outcomes, with the net result of increasing the number of available organs for transplantation.

2. A rapid, point-of-care test for recovered donor lungs to screen for compromised lungs due to aspiration (stomach acid refluxed to lungs). Concerns about aspiration are a leading cause of donor lung rejection by surgical teams. Screening donor lungs for aspiration can help optimize EVLP procedures. Net result is an increase in the number of available donor lungs for transplantation.

SQI's clinical research partner at 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 procedures (FDA approved 2019) has enabled lung transplant centers to increase the availability of donor lungs for transplant by nearly two-fold at some centers. Upon receipt of FDA market approval for the TOR $dx^{TM}$  LUNG Test, SQI intends to leverage its product offering within the EVLP market and directly to transplant hospitals.

Under autoimmune disease testing, SQI has direct-to-consumer tests, approved by the New York State Department of Health, for Celiac disease and Rheumatoid Arthritis (RA) that enable users to screen for the diseases from the comfort of their home. The direct-to-consumer RA Test can help identify and confirm RA symptoms for timely care and treatment. The direct-to-consumer Celiac Test confirms the presence of the disease and validates the effectiveness of dietary and lifestyle changes to confirm the autoimmune response is improving.

# **Business Strategy**

SQI Diagnostics, Inc. is a precision medicine company that discovers, develops, and commercializes innovative rapid diagnostic testing for healthcare providers, patients, and consumers worldwide. The Company's proprietary advanced diagnostics target organ transplant, autoimmune disease and COVID-19 testing which include the developmental direct-to-consumer COVID-19 HOME Antibody Test, the RALI-dx<sup>TM</sup> COVID-19 Severity Triage Test and the COVID-19 RALI-fast<sup>TM</sup> Severity Triage Point-of-Care (POC) Test. SQI's rapid diagnostic tests are intended to be sold to healthcare professionals so that patients can get accurate results and fast effective treatment, and direct-to-consumers so that individuals can be empowered to improve their health outcomes from the comfort of home. The Company intends to apply for EUA to the FDA and for an IO with Health Canada for the RALI-Dx<sup>TM</sup> Test in the first quarter of calendar year 2021 and for the COVID-19 HOME Antibody and RALI-fast<sup>TM</sup> POC Tests in second quarter of calendar year 2021.

We believe the consumer market is becoming more aware of the importance of having access to relevant accurate, widely available rapid diagnostic healthcare tests. Our rapid diagnostics are intended to empower people access to convenient, reliable, and private medical tests administered in their homes. Our unique strategy of merging innovative diagnostics with differentiated health management services will enable us to provide comprehensive support for health care professionals, patients, and consumers across the globe.

Our business strategy is to become a rapid diagnostics leader by maximizing our research and development, our product offering and our services platforms. Our initial target revenue streams are focused on proprietary advanced diagnostics that target organ transplant, autoimmune disease and serological testing. Our strategy includes:

- Successful completion of our diagnostic products under clinical development
- Successful marketing and business-to-business sales of our diagnostic tests
- Expansion of our commercial manufacturing and testing operations in the U.S.
- Acquisition of key talent in our business
- Potential in-licensing and out-licensing of technologies and products
- Additional development of new diagnostic products through our research and development
- Acquisition of synergistic assets complementary to our business

# **Business Highlights During the Quarter**:

# Impact of COVID-19 on our results:

During the quarter, the Company's sales were adversely impacted by COVID-19. It is anticipated that research revenues from kit sales to UHN will continue to be adversely impacted in the first quarter of the fiscal 2021, as lung transplants have been curtailed due to COVID-19. While it is not possible to determine how long the existing conditions will last, we anticipate that research kit sales with respect to transplants will revert to their pre-COVID-19 level once transplant operations return to normal.

In the fourth quarter, the Company participated in the Canada Employment Wage Subsidy ("CEWS") program where payments received under this program served to partially offset employee wages during the period. Additionally, Management continued to implement other cost reduction initiatives to conserve cash, without impacting critical R&D and manufacturing programs.

Despite the effects of COVID-19 as highlighted above, in the fourth quarter of fiscal 2020 the Company continued to actively pursue business development activities in an effort to continue to monetize its intellectual property and R&D capabilities.

# The Company advanced its clinical development of the RALI-Dx<sup>TM</sup> Test:

During the quarter, the Company made progress in advancing its clinical development for the RALI- $Dx^{\text{TM}}$  product. The Company currently intends to file its RALI- $dx^{\text{TM}}$  submission to the FDA for EUA for use in the United States as well as in Canada once its clinical development is completed.

# **Business Highlights During the Year**:

### Management and Board Changes:

During the year ended September 30, 2020, there were personnel changes to the Company's executive team as well as to the Company's Board of Directors. In February 2020, Mr. Eric Brouwer, the Company's Chief Scientific Officer took over as interim CEO until August 2020 when Mr. Rob Chioini was appointed as the Company's new CEO and a Board member. Mr. Morlan Reddock joined the Company as its Chief Financial Officer in March 2020.

Mr. Eric Schneider resigned from the Board of Directors in May 2020 and was replaced by Mr. Brouwer.

## **Financings:**

During the year ended September 30, 2020, the Company refinanced approximately \$2.5 million, including accrued and unpaid interest of \$223,000, of its \$3.2 million 10% secured non-convertible debentures that were issued in 2015 and came due in 2020. The remaining principal of such debentures, and associated accrued and unpaid interest, were repaid by the Company. The Company also completed two private placements for aggregate proceeds of approximately \$4.1 million by way of the offering of units of the Company raised approximately \$3.1 million through the exercise of warrants primarily by its three main shareholders, each of whom is also a Board member and control persons of the Company. The Company also received a portion of the approximately \$1 million grant awarded to UHN by the Canadian Institutes of Health Research to fund the validation and testing of the Company's RALI-Dx<sup>TM</sup> assay.

# **Establishment of a U.S. Subsidiary:**

As part of its larger commercial strategy, the Company established a subsidiary in the United States: SQI US, Inc. The Company intends to augment its manufacturing facility in Toronto with a second facility in the U.S. Management is currently assessing several facilities but has not yet signed an agreement.

# **Design & Manufacturing Services:**

Our Life Science Research business is designed to assist global biotechnology and pharmaceutical companies advance their research more quickly and more economically than what is currently available to them, in addition to providing better quality data.

## **Expanded Partnership and Contractor Network:**

During the year, the Company continued its innovation partnership with McMaster University Researchers to create new diagnostics technology. Sensor manufacturing innovations were published in a peer-reviewed journal; this article described how the manufacturing innovations could be applied to a COVID-19 severity test using the inflammatory marker IL-6.

The Company has also established partner relationships with US-based entities for the design of lateral flow point of care assays for detection of inflammatory markers such as IL-6 in human whole blood samples. This has been a successful strategy in accelerating product development capabilities.

## **Event(s)** Subsequent to September 30, 2020

# Successfully completed approximately \$4.5 million in financings through the exercise of warrants:

Historically, funding for our business has been done primarily through the issuance of additional common shares and associated warrants. A significant percentage of the outstanding common shares and warrants are held by three major shareholders who are also Board members and control persons of the Company.

The Company raised \$4.0 million in December 2020 through the exercise of 19,074,997 warrants at prices of \$0.20 and \$0.21 held by these three shareholders. This cash injection increases the Company's cash runway to fund operations early in the 2021 calendar year and provides flexibility to quickly deploy additional resources where required to accelerate its current R&D projects.

Additionally, post year-end several non-insiders exercised 2,248,260 warrants at exercise prices ranging from \$0.20 to \$0.21 for total gross proceeds of \$457,000.

### Acquisition of Capital Assets.

On December 3, 2020, the Company entered into an agreement to acquire three major capital assets for total consideration of approximately \$1.5 million excluding installation charges. Delivery is anticipated to be at various times during calendar year 2021. These assets, which are referred to as systems, will be used to increase the Company's manufacturing capacity. The systems are an automated liquid dispensing solution for high throughput production of multiple tests for diagnostics and life science use. The systems are used to print biologicals e.g proteins, antibodies, DNA onto a surface which becomes the basis of the SQI assay kit.

# Financial Highlights for the Quarter and Twelve-month Period

## Three months:

Total revenues for the three months ended September 30, 2020 were \$251,000 compared to \$640,000 for the equivalent period last year. Product revenue, which includes revenue from kit sales, was \$138,000 for the current quarter compared to \$299,000 for the same quarter last year. The decrease in product revenue is attributable to the absence of any platform sales in the current period.

Revenue from services in the fourth quarter were \$113,000 compared to \$341,000 in the same period last year due to lower revenue from service contracts from one specific customer.

# Twelve months:

Total revenues for the twelve months ended September 30, 2020 were \$1,023,000 compared to \$1,891,000 for the same period last year. Product revenue was \$666,000 for the current period compared to \$1,145,000 for the same period last quarter. The decrease in product revenue is due to a combination of the loss of a major customer and the negative impacts of COVID-19 on the business and operations of the Company, as one of our customers temporarily suspended operations, which adversely impacted kit sales. The Company is currently engaged in litigation with this customer for non-payment of invoices related to product sales.

Revenue from services in the current twelve-month period was \$357,000 compared to \$746,000 in the same period last year. Service revenues were primarily lower in the current period due to the recognition of revenue from a large contract to develop multiple lung transplant products in the same period last year.

# Outlook

We are currently advancing three important COVID-19 tests through clinical development with the intent to submit applications for Emergency Use Authorization to the FDA for all three. These products include the direct-to-consumer COVID-19 HOME Antibody Test, the RALI-dx<sup>™</sup> COVID-19 Severity Triage Test and the COVID-19 RALI-fast<sup>™</sup> Severity Triage POC Test.

We plan to accelerate the clinical development of our  $\text{TOR}dx^{\text{TM}}$  LUNG Test once the regulatory agencies begin to allow new non-COVID-19 device applications to be submitted. While COVID-19 has affected our reported revenues for the current periods, we believe this trend is likely to reverse as we address the needs of the COVID-19 market, seek to gain regulatory approvals and work with our partner to increase sales of our Direct to Consumer ("DTC") products.

Our existing customers in the DTC market have remained steady, with a slight decline due to COVID-19 and consumers' attention being directed toward the pandemic versus self-testing for celiac disease and RA.

# **CORPORATE FINANCING TRANSACTIONS IN FISCAL 2020**

## Private Placements

On September 25, 2019 and October 22, 2019, the Company completed a non-brokered private placement of an aggregate of 32,300,000 units of the Company at \$0.10 per unit for gross proceeds of \$3,230,000. Each unit was comprised of one common share of the Company and one common share purchase warrant. Each warrant is exercisable at a price of \$0.13 and entitles the holder thereof to acquire one common share for a period of five years from the date of issuance.

On February 14, 2020 and March 5, 2020, the Company completed a non-brokered private placement of an aggregate of 44,444,444 units of the Company at \$0.09 per unit for gross proceeds of \$4,000,000. Each unit was comprised of one common share of the Company and one common share purchase warrant. Each warrant is exercisable at a price of \$0.12 and entitles the holder thereof to acquire one common share for a period of five years from the date of issuance, subject to accelerated expiry in certain circumstances.

The Company used a portion of the net proceeds of its private placements to repay \$1,000,000 of the principal amount of certain 10% secured non-convertible debentures of the Company, plus accrued interest of \$100,000. The remaining funds were used for the Company's product commercialization and manufacturing programs, sales and marketing and for general working capital purposes.

### Debenture Extension

On January 30, 2015 and February 20, 2015, the Company issued secured debentures (the "Debentures") with principal amounts of \$1,950,000 and \$1,286,000, respectively. The Debentures bore interest at a rate of 10% and were due 60 months from the date of issuance. The Debentures matured during the quarter ended March 31, 2020. The Company repaid \$1,000,000 of Debentures that were set to expire in February 2020, and \$100,000 of accrued and unpaid interest thereon. The remaining \$2,236,000 principal amount of Debentures extended for an additional five years pursuant to the terms of extension agreements entered into with holders of such Debentures. In addition, \$223,600 of accrued and unpaid interest was added to the principal amount of the extended debentures resulting in new principal amounts of \$2,145,000 and \$314,600 as of January 30, 2020 and February 20, 2020, respectively. Please see the accompanying financial statements for additional details relating the Debenture extension and corresponding amendments.

#### Warrants and Options

In June 2020, a total of 195,000 options were exercised at prices of \$0.15 and \$0.16, respectively, for total gross proceeds of \$30,000.

In July 2020, a total of 29,011,117 warrants were exercised by certain insiders who are also control persons of the Company, at prices \$0.09 and \$0.11 for total gross proceeds of \$3,111,000.

In September 2020, a total of 2,033,333 warrants were exercised at prices of \$0.20 and \$0.21, respectively, for total gross proceeds of \$411,000.

In September 2020, a total of 70,778 options were exercised at prices \$0.16 and \$0.20, respectively, for total gross proceeds of \$12,000.

# SELECTED FINANCIAL INFORMATION

### Fourth Quarter and Full-Year Commentary

The table below summarizes quarterly financial information for the three-month and fullyear periods shown.

	Three months ended September 30, 2020 (000s)	Three months ended September 30, 2019 (000s)	Twelve months ended September 30, 2020 (000s)	Twelve months ended September 30, 2019 (000s)
Revenue	\$251	\$640	\$1,023	\$1,891
Net Loss	(\$2,815)	(\$2,807)	(\$8,571)	(\$8,021)
Net Loss Per Share	(\$0.01)	(\$0.01)	(\$0.03)	(\$0.04)
Weighted Average Shares	306,418	200,477	266,943	178,391

#### Revenues

#### Three months:

During the three and twelve-month periods ended September 30, 2020, the Company recorded revenue from the sale of custom kits, platform components as well as service revenue to our biopharma and diagnostic customers. The table below summarizes revenue by category.

	Three months ended September 30, 2020 (000s)	Three months ended September 30, 2019 (000s)	Twelve months ended September 30, 2020 (000s)	Twelve months ended September 30, 2019 (000s)
Product sales - Kits	\$138	\$103	\$557	\$949
Product sales - Platforms	-	\$196	\$109	\$196
Service revenue	\$113	\$341	\$357	\$746
Total revenue	\$251	\$640	\$1,023	\$1,891

The reduction in revenue compared to the prior year's quarter is principally due to the absence of platform sales in the current quarter and lower revenue from a major customer. The Company believes that revenue may fluctuate over the next few quarters as customers and partners react to the impact of COVID-19.

#### Twelve months:

The reduction in revenue compared to last year is principally due to the loss of a single customer which the Company ceased shipments to in 2019 due to non-payment, the absence of platform sales in the current quarter and lower revenue from a major customer. Kit sales to UHN have also been negatively impacted due to a temporary halt and fundamental changes to lung procedures as a result of COVID-19.

#### Net Loss

#### Three months:

For the quarter ended September 30, 2020, the Company recorded a net loss of \$2,815,000 (\$0.01 net loss per share) as compared to a net loss of \$2,807,000 (\$0.01 net loss per share) for the quarter ended September 30, 2019. The net loss in the current period is essentially the same as the corresponding prior year period. This year, savings in Research & Development ("R&D") and in Sales and Marketing expenses as well as lower Cost of Goods Sold, were offset by lower revenue, a portion of which is attributed to the COVID-19 pandemic, and higher Corporate and General expenses. Expenses were lower in the R&D area due to lower salaries and wages as the Company participated in the CEWS program. Laboratory costs and supplies expenses were also lower in the current quarter compared to the same period prior year due to the timing of R&D projects. Sales and Marketing expenses were lower in the current quarter last year due to lower contractor related costs as well as lower travel and marketing costs as a result of the travel restrictions imposed by COVID-19.

#### Twelve months:

For the twelve months ended September 30, 2020, the Company recorded a net loss of \$8,571,000 (\$0.03 net loss per share) as compared to a net loss of \$8,021,000 (\$0.04 net loss per share) for the year ended September 30, 2019. The net loss in the current period is higher than the net loss in the corresponding prior year period primarily due to lower revenue from one particular customer.

# **Operating Expenses**

## Three months:

Research and development ("R&D") expenses include salaries and benefits from R&D staff, consulting fees, supplies and general laboratory operating expenses. R&D expenses, excluding amortization and stock-based compensation, for the three months ended September 30, 2020 were \$843,000 compared to \$1,495,000 for the same period last year. Expenses were lower due to several factors: lower salaries and wages due to the benefit of the CEWS, and lower laboratory costs and supplies. Laboratory costs and supplies tend to vacillate due to the timing of R&D projects.

Corporate and general expenses include compensation and related costs and operating expenses not directly involved in R&D and Sales & Marketing, as well as professional fees for legal, audit, consulting and investor relations. Corporate and general expenses, excluding stock-based compensation, totaled \$1,113,000 for the three months ended September 30, 2020 as compared to \$548,000 for the three months ended September 30, 2019 resulting from increased professional fees. Professional fees were higher in the current quarter compared to the same period prior year due to higher legal and recruiting costs with respect to the search for the new CEO and to the establishment of a subsidiary in the United States. There were also increased costs associated with maintaining the Company's intellectual property portfolio.

Sales and marketing expenses, excluding stock-based compensation, decreased to \$161,000 for the three months ended September 30, 2020 compared to \$210,000 for the three months ended September 30, 2019 due to lower contractor fees on account of lower headcount as well as lower travel and marketing spend due to the COVID-19 pandemic.

Non-cash, stock-based compensation charges increased to \$551,000 for the three months ended September 30, 2020 compared to \$164,000 for the three months ended September 30, 2019. The increase was due to a signing bonus in the form of stock options that was offered to the new CEO as part of his compensation package.

### Twelve months:

Research and development expenditures, excluding amortization and stock-based compensation, for the twelve months ended September 30, 2020 were lower at \$3,617,000 compared to \$4,212,000 for the same period last year due to lower salaries and wages on account of the CEWS program (and temporary layoffs) as well as lower laboratory costs and supplies.

Corporate and general expenses, excluding stock-based compensation, totaled \$2,443,000 for the twelve months ended September 30, 2020 as compared to \$1,635,000 for the twelve months ended September 30, 2019 due to increased professional fees. Professional fees were higher in the current period compared to the same period prior year due to higher legal fees, recruiting costs, consulting costs and regulatory compliance costs.

Sales and marketing expenses, excluding stock-based compensation, decreased to \$966,000 for the twelve months ended September 30, 2020 compared to \$1,174,000 for the twelve months ended September 30, 2019 due to lower contractor fees as well as lower travel and marketing costs.

Non-cash, stock-based compensation charges increased to \$856,000 for the twelve months ended September 30, 2020 compared to \$593,000 for the twelve months ended September 30, 2019. The increase was due to a signing bonus that was offered to the new CEO as part of his compensation package.

## Liquidity and Balance Sheet

Management expects further investments in our planned R&D programs, Clinical & Regulatory, product development and commercialization efforts for its pipeline of custom consumable kits, new products and platforms, and sales and marketing initiatives into fiscal 2021.

The Company believes it has sufficient liquidity to meet its current obligations as they come due in the second fiscal quarter. The continuation of the Company's research, development and commercialization activities is dependent upon its ability to generate product or service revenues or to finance its operations through further equity and or debt financings. Factors that will affect our anticipated cash usage in the future, and for which additional funding may be required include, but are not limited to, the pace of expansion of our US operations, the timing of both R&D activities and regulatory decisions by the FDA and Health Canada.

Operating activities for the quarter ended September 30, 2020, were financed by cash on hand.

As at September 30, 2020, current assets were \$3,668,000 including \$2,596,000 of cash compared to \$4,494,000 including \$3,444,000 of cash at September 30, 2019. As at September 30, 2020, the Company had a \$2,203,000 working capital surplus compared to a deficit of \$217,000 at September 30, 2019. The higher surplus is due to a change in classification of the debentures which matured and were subsequently extended; this extension changed the classification from a current liability to a long-term liability in the year. See "Corporate Finance Transactions in Fiscal 2020" for a discussion of the private placements, debenture amendments and warrant and option exercises completed during fiscal 2020.

Cash used in investing activities for the three months ended September 30, 2020 was \$43,000 (fiscal 2020 - \$182,000) as compared to \$29,000 for the three months ended September 30, 2019 (fiscal 2019 - \$200,000). Cash used in investing activities were predominantly for information technology upgrades, leasehold improvements, lab equipment, and patents and trademarks while cash used in the prior year were in respect of laboratory equipment and patents.

The Company has approximately \$2.5 million in long-term debt with a maturity of approximately four years.

## **Outstanding Capital Stock**

As at January 27, 2021, there were 329,419,020 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 at January 27, 2021:

Number of		
Warrants (000's)	<b>Exercise Price</b>	Maturity
3,220	\$0.21	March 10, 2022
51,384	\$0.20	December 20, 2022 – August 24, 2023
3,200	\$0.11	March 1 and 8, 2024
13,429	\$0.17	July 12, 2024
32,300	\$0.13	September 25 and October 22, 2024
106	\$0.09	January 30, 2025
622	\$0.085	February 20, 2025
44,444	\$0.12	February 14, 2025 and March 5, 2025
148,705		

The Company had the following stock options outstanding under its stock option plan at January 27, 2021:

Number of Options (000's)	Range of Exercise Prices	Weighted average time to maturity
1,372	\$ 0.07 - 0.14	ľ
,	\$ 0.07 - 0.14 \$ 0.15 - 0.22	4.08 years
37,356 3,366	0.13 - 0.22 0.23 - 0.30	8.13 years
,	\$ 0.23 - 0.50	4.77 years
42,094		

On August 17, 2020, the Company granted to Mr. Chioini an aggregate of 29,835,062 stock options ("Options") to purchase common shares in the capital of the Company ("common shares") for a period of ten years, at an exercise price of \$0.195 per share (the "CEO Option Grant"), subject to earlier termination in certain circumstances. The Options vest and become exercisable as to one-third on each of the first, second and third anniversaries of the date of the grant, subject to certain conditions and subject to accelerated vesting in certain circumstances. The CEO Option Grant is subject to disinterested shareholder approval (i.e., excluding the votes attached to shares beneficially owned by Mr. Chioini and his associates) and the final approval of the TSXV.

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

The Company has no off-balance sheet arrangements.

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

## 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 financial statements for the year ended September 30, 2020. Refer to the audited consolidated financial statements for the year ended September 30, 2020 for discussion on accounting policies and estimates that are most important in assessing, understanding and evaluating the Company's consolidated financial statements. Changes in these estimates and assumptions could have a material impact on the Company's consolidated financial statements.

## **RECENT ACCOUNTING PRONOUNCEMENTS**

#### (a) Adoption of New Accounting Standard

IFRS 16 Leases was issued in January 2019 and replaces IAS 17 Leases. Under IAS 17, lessees were required to make a distinction between a finance lease and an operating lease. If the lease was classified as a finance lease, a lease liability was included on the statement of financial position. IFRS 16 now requires lessees to recognize a right of use asset and lease liability reflecting future lease payments for virtually all lease contracts. The right of use asset is treated similarly to other nonfinancial assets and depreciated accordingly. The lease liability accrues interest. The IASB has included an exemption for certain short-term leases and leases of low value assets; however, this exemption can only be applied by lessees. Under IFRS 16, a contract is, or contains, a lease if the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration. Control is conveyed where the customer has both the right to direct the identified asset's use and obtain substantially all the economic benefits from that use. IFRS 16 is effective for annual periods beginning on or after January 1, 2019 with early adoption permitted if IFRS 15, Revenue from Contracts with Customers, is also applied. The Company adopted this standard on October 1, 2019. Please see the accompanying consolidated financial statements for full disclosure and analysis of the impact this adoption had on the Company's reported results for the quarter and year-to-date.

# **RISK FACTORS**

An investment in our common shares involves a number of risks. In addition to the other information contained in this Management Discussion and Analysis, including our consolidated financial statements and related notes for the year ended September 30, 2020, investors should give careful consideration to the following risk factors. Any of the matters highlighted in these risk factors could have a material adverse effect on our business, results of operations and financial condition, causing an investor to lose all, or part of their investment.

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

# **Risks Related to Our Business and Strategy**

# Uncertain Future Capital Needs and Additional Financing

We believe that our existing cash and cash equivalents will be sufficient to meet our anticipated cash requirements for approximately the next 4 months. As such, we will need to raise additional capital to:

- maintain our current operations to address custom projects and to deliver on contracts currently in place;
- expand the commercialization of our products;
- manufacture SQI platforms and products; and
- further our research and development.
- advance our Clinical & Regulatory program

Our future liquidity and funding requirements are uncertain and depend on many internal and external factors.

If we raise additional funds by issuing equity securities, our shareholders may experience dilution. Debt financing, if available, may involve further covenants, pledges and restrictions. Any debt or additional equity financing may contain terms that are not favourable to us or our shareholders. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish some rights to our technologies or our products, or grant licenses on terms that are not favourable to us.

If we do not have, or if we are unable to obtain additional funds on acceptable terms, on a timely basis, or at all, we may have to delay development or commercialization of our products or license to third parties the rights to commercialize products or technologies that we would otherwise seek to commercialize. We also may have to liquidate some or all of our assets, reduce the scope of or eliminate some or all of our development programs, reduce marketing, customer support or other resources devoted to our products, or cease

operations. Any of these factors could harm our business, financial condition and results of operations.

# History of Losses

We have limited commercial history and have incurred significant losses in each fiscal year since inception. As of September 30, 2020, we had an accumulated deficit of \$103.4 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.

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.

## **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 standards could materially affect our ability to manufacture or market our products successfully, and could therefore have a material adverse effect on our business.

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 of 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 sqid**lite** 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 thirdparty payors.

# Key Personnel

Our performance depends substantially upon the performance of our senior management and key scientific and technical personnel, including our Chief Executive Officer, Rob Chioini, our Chief Scientific Officer, Dr. Eric Brouwer and our Chief Financial Officer, Morlan Reddock. If we are unable to attract and retain skilled and experienced personnel, or if we lose the services of any member of our senior management or our key scientific or technical staff, it could have a material adverse effect on our business, financial condition, and results of operations.

## 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 the first quarter of the fiscal 2021 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 year ended September 30, 2020, the Company participated in the Canada Employment Wage Subsidy program, where payments of \$681,000 received under this program served to partially offset employee wages during the period.

## **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. 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. Our pending Canadian, U.S. and foreign patent applications may not issue as patents or may not issue in a form that will be sufficient to protect our proprietary technology and gain or keep our 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.

### **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

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.

Management seeks to mitigate these risks, and others, primarily by retaining experienced employees and advisors who have expertise in the scientific, medical, business, regulatory, manufacturing and operational disciplines of automated platform integration and immunoassay diagnostic test development.

During the current reporting period, the Company earned service revenues and revenues from the sale of its diagnostic kits and we believe that a great deal of progress has been achieved in proving our value to several large global pharmaceutical and diagnostic customers. We continue to advance our relationships with these and other customers to the stage where we expect recurring sales of testing platforms and consumables to 'marketready' customers. However, additional platform placements and commercial sales are required to reach a position of cash flow break-even. The continuation of the Company's research, development and commercialization activities along with investment in marketing and sales depends on the Company's ability to successfully manage its growth, investment in continued pipeline development and its cash requirements.

The Company is exposed to market risks related to changes in interest rates and foreign currency exchange rates, which could adversely affect the value of our current assets and liabilities. We do not believe that the results of operations or cash flows would be affected to any significant degree by a sudden change in market interest rates relative to our cash investment, due to the prime-interest-rate-based nature of the investment.

We have not entered into any forward currency contracts or other financial derivatives to hedge foreign exchange risk. We are subject to foreign exchange rate changes that could have a material effect on future operating results or cash flows.

Management will continue to review the Company's financial needs and to seek additional capital as required from sources that may include equity financing, debt financing, collaborative projects and licensing arrangements; however, there can be no assurance that such additional funding will be available or if available, whether acceptable terms can be obtained. To date, we have mitigated our financing risks through the on-going financial support of three key insider shareholders who are also control persons of the Company, have invested significantly in the success of the Company.

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

The accompanying financial statements have been prepared by management in accordance with International Financial Reporting Standards. For quarterly reporting periods, the Company's 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 these financial statements are the responsibility of management. In addition, 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 financial statements.

In support of this responsibility, management maintains a system of internal controls to provide 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 provide 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 provide 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, 2020;

(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 three-month period ended September 30, 2020; 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 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 financial statements prior to 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<sup>™</sup>: Our bench-top diagnostic system – fully automated bench top microarray processing system

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