



**SQI DIAGNOSTICS INC.**

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

**June 30, 2020**

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

*This Management’s Discussion and Analysis (“MD&A”) covers the condensed interim financial statements for the three and nine months ended June 30, 2020 and 2019. The annual audited financial statements and MD&A for the year ended September 30, 2019 and the most recent Annual Information form (“AIF”) 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 was prepared by management using information available as of August 26, 2020.*

*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**

Historically, SQI Diagnostics has been focused on its life science research business that develops clinical grade multiplexed microarray and molecular assays for the pharmaceutical research, animal health, and clinical diagnostics markets. These products and services enable customers to perform large numbers of blood-based tests for their clinical diagnostic and research testing needs – quickly, inexpensively and accurately.

The Company is now expanding its business model into the rapid diagnostic testing market and intends to increase its manufacturing footprint considerably to commercialize our proprietary rapid diagnostic tests. Initially, we will be focusing on three business units targeting organ transplant, autoimmune disease and serological testing. Under serological testing, we have an immediate priority to commercialize our developmental direct-to-

consumer Covid-19 At-Home Antibody Test Kit and our Covid-19 Patient Triage Test (RALI-Dx™).

As a result of our strategic advancement, SQI Diagnostics, Inc. is a precision medicine company that discovers, develops, manufactures and commercializes innovative rapid diagnostic tests for healthcare providers, patients and consumers worldwide. The Company's proprietary advanced diagnostics target organ transplant, autoimmune disease and serological testing, which include a developmental COVID-19 Patient Triage Test (RALI-Dx™) and a direct-to-consumer COVID-19 At-Home Antibody Test Kit. SQI's advanced rapid diagnostic tests are sold to healthcare professionals so patients can get accurate results and fast effective treatment, and direct-to-consumers so they can take action to improve their health outcomes from the comfort of their home.

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. Specifically, we are developing a suite of multi-biomarker tests to assess the health of a donor organ prior to transplant. The Company's TOR-Dx™ Lung Test can detect inflammation at the molecular level enabling surgeons to make a "go" or "no-go" decision on initiating transplantation; there is currently no other such test. SQI has partnered with Toronto General Hospital/University Health Network (UHN) Hospitals, one of the largest health and medical research organizations in North America for the TOR-Dx™ Lung Test clinical development program. The Toronto Lung Transplant Program is the largest in the world. UHN's Toronto Lung Score (TLS), which is provided by SQI's TOR-Dx™ Lung Test, has the potential to be adopted world-wide as the keystone diagnostic tool to assess donor organ suitability for transplant.

Pioneered in Toronto by surgeons at Toronto General Hospital in the 1980s, lung transplantation has become a life-saving procedure for patients with end-stage lung disease. The worldwide field of lung transplantation has grown to approximately 4,500 transplants every year. Lung transplant surgery is expensive costing approximately \$1 million per surgery. There are approximately 11,000 donor lungs available for transplant annually, however the great majority are discarded. This is largely attributed to the surgeons having to make their decision on whether an organ is healthy to transplant based on a visually evaluation. Upon regulatory approval as a medical device, the TOR-Dx™ Lung Test will enable the surgeon to determine if the donor lung is healthy enough for transplant or if should be discarded due to the occurrence of inflammation at the molecular level.

In February of 2019, SQI formed a partnership with UHN's Toronto Lung Transplant Program and developed a multiplexed test to determine the suitability for transplant of donor lungs. The biomarkers that formed the basis for this test had been the subject of ground-breaking research by UHN scientists. Within a few months, SQI's scientists developed a highly accurate test that provided results in approximately 45 minutes, reduced from three hours.

This dramatic shortening in testing time, coupled with the ability to determine the presence of inflammation, enables surgeons to make "go", "no-go" decision on a lung's viability

for transplant surgery. This breakthrough should increase the number of healthy lung transplants significantly in Canada and the US while decreasing the number of healthy discarded lungs, and save hospitals millions of dollars while, offering the same benefits to transplant surgeons and hospitals across the globe. SQI is working with agencies in both the U.S. and Canada to submit the TOR-Dx™ Lung Test for regulatory approval.

SQI's product pipeline has expanded significantly over the past year to include additional organ-transplant products which are currently in development to address the challenges of organ transplantation:

1. A quantitative test expanded from the TOR-Dx™ Lung Test that enables the monitoring and guidance of therapeutic treatments of the donor lung while on Ex Vivo Lung Perfusion ("EVLP"). This test will 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. The net result is an increase in the number of available donor lungs for transplantation.

In addition to SQI's innovation and product leadership, our 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 EVLP procedures (cleared by FDA in 2019) has enabled lung transplant centers to increase the availability of donor lungs for transplant by nearly two-fold at some centers.

SQI intends to develop additional, similar diagnostic tests designed to increase the chance of successful organ transplant for the kidney and the liver after regulatory approval of the TOR-Dx™ Lung Test.

Under autoimmune disease testing, SQI has a direct-to-consumer Celiac Disease and Rheumatoid Arthritis (RA) Test that enables people to screen for the disease from the comfort of the home.

- The direct-to-consumer RA Test can help identify and confirm RA symptoms for early and preventative care.
- The direct-to-consumer Celiac Test is the only test that confirms the disease and that can also validate the effectiveness of dietary and lifestyle changes to confirm the autoimmune response is improving.

The Company intends to increase commercialization efforts considerably for its direct-to-consumer Celiac Disease and RA tests which are now available.

Under serological testing, SQI is fast-tracking the development of a direct-to-consumer COVID-19 Antibody Home Test Kit to detect the presence of SARS-CoV-2 antibodies in the blood. The Covid-19 Antibody Test Kit will determine if someone has been exposed to the SARS-CoV-2 virus and the degree of exposure and possible immunity to it. SQI's COVID-19 Antibody Test Kit will be highly accurate >98%, and upon FDA Emergency Use Authorization will be the first or one of the first antibody tests shipped directly to the consumer home or business so individuals won't have to travel to a clinic or hospital to be tested for the presence of SARS-CoV-2 antibody.

SQI is also fast-tracking the development of a COVID-19 Triage Test called the RALI-Dx™. The RALI-Dx test is an Inflammatory Response Panel that is comprised of six cytokine biomarkers indicative of the “cytokine storm” that is associated with acute lung injury and ultimately patient outcome. The RALI-Dx delivers results in under an hour and gives the clinician insight into whether a patient with COVID-19 (or Flu or Pneumonia) can be treated and released for self-monitored home care, needs to be admitted to a standard hospital unit, or is likely to develop severe life-threatening symptoms requiring immediate intensive care unit (ICU) admittance and advanced respiratory care measures. This ability to effectively triage COVID-19 (or Flu or Pneumonia) patients would be a diagnostic industry first.

## **Business Strategy**

SQI Diagnostics, Inc. is a precision medicine company that discovers, develops, manufactures and commercializes innovative rapid diagnostic tests for healthcare providers, patients and consumers worldwide. The Company's proprietary advanced diagnostics target organ transplant, autoimmune disease and serological testing, which include a developmental COVID-19 Patient Triage Test (RALI-Dx™) and a direct-to-consumer COVID-19 At-Home Antibody Test Kit. SQI's advanced rapid diagnostic tests are sold to healthcare professionals so patients can get accurate results and fast effective treatment, and direct-to-consumers so they can take action to improve their health outcomes from the comfort of their home.

Now more than ever, we see the importance of accurate, widely available rapid diagnostic tests. With our rapid diagnostics we are empowering people to access convenient, reliable, private medical tests directly 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 global, rapid diagnostics leader by maximizing our research, products and services platform. Our initial target revenue streams are focused on proprietary advanced diagnostics that target organ transplant, autoimmune disease and serological testing, which include a developmental COVID-19 Patient Triage Test (RALI-

Dx™) and a direct-to-consumer COVID-19 At-Home Antibody Test Kit. Our strategy to achieve our goal includes:

- Expansion of our commercial and manufacturing operations in the US;
- Acquisition of key, exceptional talent in our business
- Completion of our medical device products under clinical development
- Evaluation of potential licensing agreements for our technology and product and synergistic products
- Evaluation of potential synergistic assets that are complementary to our existing and future products and services.

### **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 as customers and partners reacted to the changing landscape. It is anticipated that revenues from kit sales to the University Health Network ("UHN") may continue to be adversely impacted in the fourth quarter of the fiscal year, as lung transplants have been significantly curtailed in the short term. While it is not possible to determine how long the existing conditions will last, we anticipate that kit sales in respect of transplants, will revert to their pre-COVID level once transplant operations return to normal.

In the third quarter, the Company furloughed a portion of its workforce in order to develop a robust business continuity plan to ensure the safety of its employees amid the COVID-19 pandemic. A corollary of this action was a reduction in compensation costs during the period. The Company also participated in the Canada Employment Wage Subsidy ("CEWS") for those employees that remained as active and on its payroll. Additionally, Management implemented 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 third quarter of fiscal 2020 the Company continued to actively pursue business development activities in an effort to continue to monetize its intellectual properties and R&D capabilities. These activities have begun to bear fruit as the Company made progress on several ongoing initiatives, deepened relationships with existing partners and advanced discussions with several BioPharma target customers, ultimately resulting in a signed agreement subsequent to the quarter, to develop an assay.

#### **The Company's COVID-19 study in conjunction with the UNH made significant progress:**

During the quarter, the Company made solid progress in advancing its RALI-Dx product to determine if it can be used as a triage test for patients presenting with COVID-19 symptoms. The RALI-Dx™ Inflammatory Response Panel is a multiplexed assay that

contains specific biomarkers linked to inflammation caused by lung injury. It is now widely known that the reason the health of some people who have COVID-19 deteriorates drastically and quickly, while others experience mild or no symptoms at all, is due to inflammation. This inflammation is measured by biomarkers called cytokines. SQI has adapted the work done with its partner UHN on the TORdx™ LUNG assay to these specific cytokines that have been shown to positively predict a patient's health trajectory. The results of the assay will let an Emergency Department physician know whether or not the patient can be sent home for self-monitoring, needs to be admitted to a basic hospital floor, or should immediately be admitted to the ICU for advanced care, before the disease manifests critical symptoms. This means that two patients with identical symptoms could have very different health trajectories. Being able to accurately predict how the patient's health will progress would enable clinicians to triage patients appropriately, thereby improving outcomes and reducing costs. Of critical importance, this test can be performed in an automated fashion in under 60 minutes. The Company, in collaboration with UHN, is nearing completion of its initial study to determine viability of this test. Upon successful completion of the trial, the Company plans to submit to the FDA for Emergency Use Authorization ("EUA") for use in the United States as well as Canada.

**Completed a sqid-X® sale to the University of Buffalo and establish COVID-19 triage testing in a US CLIA lab:**

In addition to adding to our capital equipment installed-based in the United States, the sqid-X® sale positions the Company to conduct parallel COVID-19 studies in both Canada and the United States. This study will be done at the University of Buffalo and will augment the Company's study with UHN as mentioned below. This also puts SQI in a position to potentially run commercial, clinical samples for the region once the test receives Emergency Use Authorization.

**Successfully completed a \$3.1 million financing through the exercise of warrants:**

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

The Company raised \$3.1 million in June through the exercise of warrants held by these three shareholders. This cash injection increases the Company's cash runway to fund operations early into the 2021 calendar year and provides flexibility to quickly deploy additional resources where required to accelerate current R&D projects.

## **Event(s) subsequent to June 30, 2020**

### ***Appointment of new CEO and Director:***

On August 18, 2020, the Company announced the appointment of Rob Chioini as its CEO and member of its Board of Directors. Eric Brouwer, who served as interim CEO will continue in his role as Chief Scientific Officer.

Mr. Chioini was the Founder, Chairman and CEO of Rockwell Medical, Inc. (NASDAQ: RMTI) for 23 years (1995-2018), where he provided executive leadership for a publicly traded, vertically integrated, pharmaceutical drug and medical device company that he grew to four manufacturing plants, five distribution facilities and approximately 330 employees servicing the U.S. and global dialysis healthcare market. His experience spans all phases of starting and building the business, from inception into a successful \$900 million pharmaceutical drug and medical device enterprise. Mr. Chioini led a successful IPO on the NASDAQ stock exchange in 1998 and proceeded to transform the renal industry with the launch of multiple, innovative products that became standard of care, while expanding market share and building and strengthening the company's brand. He identified and licensed worldwide rights to proprietary technologies and successfully raised approximately \$250 million to fund successful human clinical studies for the development and FDA approval of an innovative, first-in-class iron replacement therapy to treat dialysis patients suffering from severe anemia. Mr. Chioini has extensive expertise in understanding all facets of business development, including creating and building a culture of excellence, new product innovation, IP, licensing, marketing, sales, clinical drug development, pharmaceuticals, medical devices, finance, manufacturing, distribution, commercialization, strategic positioning and U.S. Congressional and Government Agency relations. Mr. Chioini attended Michigan State University and received a Bachelor of Arts Degree in Advertising in 1987.

### ***Established a US subsidiary: SQI US, Inc.:***

Subsequent to the quarter, the Company incorporated a wholly owned subsidiary named SQI US, Inc., in the United States. SQI US, Inc. is based in Michigan and currently has limited operations but is expected to play a pivotal role as the Company embarks on its expansion plan.

## **Financial Highlights for the Quarter and Nine-month Period**

### ***Three months:***

Total revenues for the three months ended June 30, 2020 were \$296,000 compared to \$540,000 for the equivalent period last year. Product revenue, which includes revenue from kit sales was \$266,000 for the current quarter compared to \$313,000 for the same quarter last year. The decrease in product revenue is attributable to the loss of one customer, which accounted for a material percentage of revenue in the same prior year period. Excluding the effect of the lost customer, kits sales were up 74% over the equivalent period last year.

Revenue from services in the third quarter were \$30,000 compared to \$227,000 in the same period last year. Service revenues were lower in the third quarter of 2020 compared to the same period prior year due to the recognition of revenue from a large contract to develop multiple lung transplant products in the third quarter of 2019.

***Nine months:***

Total revenues for the nine months ended June 30, 2020 were \$772,000 compared to \$1,251,000 for the same period last year. Product revenue was \$528,000 for the current period compared to \$846,000 for the same period last quarter. The decrease in product revenue is attributable to the absence of revenue from one customer, which was responsible for a sizable percentage of product revenue in the same period prior year.

Revenue from services in the current nine-month period was \$244,000 compared to \$405,000 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.

**Expanding Sales Pipeline**

Many of the Company targeted Biopharma customers are slowly returning to work after a five-month hiatus due to the COVID-19 pandemic. The Company's sales funnel continues to expand with many promising new high-value opportunities, some of which if successful are anticipated to occur by the second quarter of fiscal 2021.

**Outlook**

We achieved significant product development milestones in our TORdx LUNG™ product and are in varying stages of several other initiatives as described earlier in the Quarterly Highlights. Our technology is bringing a significant, practical advantage to lung transplant surgeons and we are optimistic that we will return to revenue growth following the softness experienced during the past two quarters as a result of COVID-19. 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 DTC products.

There are approximately 100 lung transplant centers in the US and 4 in Canada. We will initially target the 20 highest volume transplant centers then direct our efforts to the remaining centers. The use model we have developed with our partners involves the use of several TORdx tests per patient: one or more TORdx *rapid* tests including one just after recovery of the donor lung, and one TORdx test during EVLP. As transplant surgeons and Lung Bioengineering centers shift to longer EVLP times we could see additional TORdx tests being consumed.

We are optimistic that our research partnership with the world-renowned Toronto Lung Transplant Program at UHN will enable us to create a point of care test for surgeons to more accurately assess the suitability of lungs for transplant – and similar tests for different organs, each performing essentially the same life-saving function. We are equally optimistic that this relationship will result in organic growth of additional products in the organ transplant segment and other lung related areas.

Our existing customers in the Direct to Consumer (“DTC”) market in our CLIA business 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.

## **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 comprises 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 comprises 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 the Private Placement 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 are expected to be 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 redeemable 60 months from the date of issuance. The Debentures matured during the quarter ended March 31, 2020 with \$1,000,000 of the February 2020 tranche and \$100,000 of accrued interest related to this amount being repaid by the Company. The maturity dates of the existing \$2,236,000 Debentures were extended for an additional five years in agreement with the holders of the financial instruments. In addition, \$223,600 of accrued interest was added to the principal

amount of the existing 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 on the amendment.

### *Warrants and Options*

During June 2020, a total of 29,011,117 warrants were exercised by certain insiders of the Company for total gross proceeds of \$3,111,000. A total of 25,000,005 of the warrants issued in connection with a March 2019 private placement were exercised at a price \$0.11 per share while 4,011,112 warrants issued in connection with the debt refinancing conducted in this fiscal year's second quarter being exercised at a price \$0.09 per share. the

On June 10<sup>th</sup>, 195,000 options were exercised at a weighted average price \$0.15 for gross proceeds of \$30,000.

## **SELECTED FINANCIAL INFORMATION**

### **Third Quarter and Year-to-date Commentary**

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

	Three months ended June 30, 2020 (000s)	Three months ended June 30, 2019 (000s)	Nine months ended June 30, 2020 (000s)	Nine months ended June 30, 2019 (000s)
Revenue	\$ 296	\$ 540	\$ 772	\$ 1,251
Net Loss	\$ (1,473)	\$ (1,888)	\$ (5,756)	\$ (5,214)
Net Loss Per Share	\$ (0.01)	\$ (0.01)	\$ (0.02)	\$ (0.03)
Weighted Average Shares	277,149	186,609	253,688	170,948

## **Revenues**

### *Three months:*

During the three and nine-month periods ended June 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		Three months ended		Nine months ended		Nine months ended	
	June 30, 2020		June 30, 2019		June 30, 2020		June 30, 2019	
	(000s)		(000s)		(000s)		(000s)	
Product sales - Kits	\$	168	\$	313	\$	419	\$	846
Product sales - Platforms		98		-		109		-
Service revenue		30		227		244		405
Total revenue	\$	296	\$	540	\$	772	\$	1,251

The reduction in revenue compared to the prior year's quarter is principally due to the loss of a single customer, which the Company ceased shipments to in 2019 due to non-payment. The Company believes that revenue may fluctuate over the next few quarters as customers and partners react to the impact of COVID-19.

*Nine months:*

The reduction in revenue compared to the equivalent period is principally due to the loss of a single customer which the Company ceased shipments to in 2019 due to non-payment. 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 June 30, 2020, the Company recorded a net loss of \$1,473,000 (\$0.01 net loss per share) as compared to a net loss of \$1,888,000 (\$0.01 net loss per share) for the quarter ended June 30, 2019. The net loss in the current period is lower than the net loss in the corresponding period prior year due to lower Research & Development ("R&D") and Sales and Marketing expenses, which was partially offset by lower revenue, a portion of which is attributed to the COVID-19 pandemic. Expenses were lower in the R&D area due to lower salaries and wages as the Company participated in the Canada Emergency Wage Subsidy ("CEWS") program and also received a Scientific Research and Experimental Development Tax Credit ("SRED"), while a SRED credit was received in the second quarter of the prior year. 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 compared to the same 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.

*Nine months:*

For the nine months ended June 30, 2020, the Company recorded a net loss of \$5,756,000 (\$0.02 net loss per share) as compared to a net loss of \$5,214,000 (\$0.03 net loss per share) for the quarter ended June 30, 2019. The net loss in the current period is higher than the

net loss in the corresponding period prior year primarily due to lower revenue as expenses were essentially flat when compared to the corresponding period prior year.

## **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 June 30, 2020 were \$572,000 compared to \$1,145,000 for the same period last year. Expenses were lower due to several factors; the presence of a SRED tax credit in the current period while absent in the comparative period, lower salaries and wages due to the benefit of the CEWS, and to 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 \$523,000 for the three months ended June 30, 2020 as compared to \$397,000 for the three months ended June 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 fees in respect of the search for the new CEO and for 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 June 30, 2020 compared to \$316,000 for the three months ended June 30, 2019 due to lower contractor fees on account of lower headcount as well as lower travel and marketing spend, reflecting higher activity levels in 2019 prior to the travel restrictions imposed in March 2020 due to the COVID-19 pandemic.

Non-cash, stock-based compensation charges decreased to \$70,000 for the three months ended June 30, 2020 compared to \$130,000 for the three months ended June 30, 2019. The reduction is a result of forfeitures of stock options associated with the departure of certain employees as well as a delay in the granting of stock option to employees when compared to the same period in 2019.

### *Nine months:*

Research and development expenditures, excluding amortization and stock-based compensation, for the nine months ended June 30, 2020 were essential flat at \$2,774,000 compared to \$2,717,000 for the same period last year as lower salaries and wages on account of the benefits from the CEWS program were offset by higher laboratory costs and supplies as well as a lower SRED tax credit.

Corporate and general expenses, excluding stock-based compensation, totaled \$1,330,000 for the nine months ended June 30, 2020 as compared to \$1,087,000 for the nine months ended June 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 and regulatory compliance costs.

Sales and marketing expenses, excluding stock-based compensation, decreased to \$805,000 for the nine months ended June 30, 2020 compared to \$964,000 for the nine months ended June 30, 2019 due to lower contractor fees as well as lower travel and marketing costs.

Non-cash, stock-based compensation charges decreased to \$305,000 for the nine months ended June 30, 2020 compared to \$429,000 for the nine months ended June 30, 2019. The reduction is a result of forfeitures of stock options associated with the departure of certain employees as well as a delay in the granting of stock option to employees for fiscal 2019 performance, when compared to the same period in 2019.

### **Liquidity and Balance Sheet**

Management expects further investments in our planned R&D programs, product development and commercialization efforts for its pipeline of custom consumable kits, new products and platforms, and sales and marketing initiatives throughout the remainder of fiscal 2020 and into fiscal 2021.

The Company believes it has sufficient liquidity to meet its current obligations as they come due in the next two quarters. 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 June 30, 2020, were financed by cash on hand.

As at June 30, 2020, current assets were \$5,388,000 including \$4,320,000 of cash compared to \$4,494,000 including \$3,444,000 of cash at September 30, 2019. As at June 30, 2020, the Company had a \$3,975,000 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 period. Higher cash from financing activities also contributed to the working capital surplus. See page 11 and 12 for the discussion of the private placement, debenture amendments, warrant and option exercises completed during the fiscal year thus far.

Cash used in investing activities for the three months ended June 30, 2020 was \$55,000 as compared to \$36,000 for the three months ended June 30, 2019. Cash used in investing

activities were predominantly for computer infrastructure, lab equipment, and patents and trademarks while cash used in the same quarter 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 slightly less than five years.

## Outstanding Capital Stock

As at August 26, 2020, there were 305,991,652 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 August 26, 2020:

<b>Number of Warrants (000's)</b>	<b>Exercise Price</b>	<b>Maturity</b>
7,631	\$0.52	December 15 and 21, 2020
463	\$0.20	December 20, 2020
22,970	\$0.21	March 10, 2022
54,527	\$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
179,692		

The Company had the following stock options outstanding under its ESOP Plan at August 26, 2020:

<b>Number of Options (000's)</b>	<b>Range of Exercise Prices</b>	<b>Weighted average time to maturity</b>
9,268	\$ 0.07 - 0.25	3.10 years
1,738	\$ 0.30	0.55 years
178	\$ 0.40 – 0.60	0.06 years
11,184		

## 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 financial statements for the year ended September 30, 2019. Refer to the audited consolidated

financial statements for the year ended September 30, 2019 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 2016 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.

### **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 June 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 June 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.

## **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, 2019, 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**

*Our future capital needs are uncertain and additional financing may be required.*

*We have a limited commercial history and a history of losses.*

*The competitive market for our products is changing and evolving.*

*Our success depends, in part, on gaining market acceptance of our products.*

*Our market has complex regulatory compliance requirements.*

*We may experience rapidly changing technology and customer requirements.*

*New diagnostic products, and improvements to existing diagnostic products, require significant research, development, testing and investment prior to any final commercialization.*

*We have limited experience in the marketing and distribution of our products.*

*We rely on key suppliers.*

*We may be subject to legislative or regulatory change.*

*Partner grants may not be available in the future. This may delay progress in product development.*

*We rely on key personnel.*

*We may experience development or manufacturing delays.*

*Our products may be subject to unknown defects or errors.*

*We may experience foreign exchange fluctuations.*

### **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.

### **Risks Related to Intellectual Property**

*Our commercial success depends, in part, upon our ability to protect our intellectual property and proprietary technologies.*

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

*There may be volatility of our share price that does not reflect the long-term value of the Company.*

*There may not be an active market for our shares, which could limit investors ability to exit positions.*

*We have not paid dividends.*

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 ‘market-ready’ 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 have invested significantly in the success of the Company.