



**SQI DIAGNOSTICS INC.**

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

**December 31, 2019**

## **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 months ended December 31, 2019 and 2018. 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 at February 24, 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**

### **SQI: Science, Quality, Innovation – One blood test, many results, all at once**

SQI Diagnostics uses advanced technologies to develop and sell testing kits, services and automated testing systems to hospitals and clinicians, pharmaceutical and diagnostic testing companies.

Our products and services allow them to perform very large numbers of blood-based tests for their clinical and research diagnostic testing needs – quickly, cheaply and accurately. As we say: “One test, many results, all at once.”

SQI Diagnostics Inc. was founded in 1999 to capitalize on two emerging opportunities. First, the large and growing number of blood tests performed to diagnose the state of a patient’s disease. Second, the belief that reducing both the effort and associated costs of

these tests would create a profitable business that, in turn, would significantly benefit the life sciences industry.

Over the past 20 years, SQI has advanced from being largely an R&D enterprise to a commercially-driven one. In 2007, the Company began trading on the TSX Venture Exchange and today enjoys an expanding number of revenue streams, propelled by the growing demands of global diagnostic and pharmaceutical firms for much faster and more accurate testing.

### Saving Lives. Evolving SQI

In the first quarter of fiscal 2020 we have continued to advance the on-going evolution of SQI in the 2019 fiscal year.

Of particular note during the first quarter of fiscal 2020 is our continuing pioneering work in using multi-biomarker tests to boost the number of ‘good’ lungs available for transplant. Specifically, we are developing a suite of multi-biomarker tests to assess the health of a donor organ prior to transplant and has partnered with the University Health Network (UHN) Toronto Lung Transplant Program, the largest lung transplant program in the world. UHN’s Toronto Lung Score (TLS) , which is provided by SQI’s TORdx LUNG test, is expected to be adopted world-wide as the diagnostic tool to assess donor lungs for suitability for transplant into recipients while the donor lung is being treated on another UHN invention, Ex Vivo Lung Perfusion (EVLP). Follow the [link](#) to UHN’s ex vivo perfusion information on the repair of donor organs for lungs, livers and kidneys.

Lung transplantation is a lifesaving procedure for patients with end-stage lung disease. The surgical technique for transplantation was pioneered in Toronto in the 1980s. The worldwide field of lung transplantation has grown to ~4,500 transplants every year.

The partnership with UHN has expanded significantly over the past year to include the following products:

				
Use Case	Go-no-go diagnostic for transplant	Quantitative diagnostic for EVLP <i>theranostic</i>	Point of Care rapid diagnostic	Point of Care lung aspiration
Testing Output	Quantitative <45 minutes Toronto Lung Score	Toronto Lung Score plus <i>theranostic</i>	Lung Status <i>Snap Shot</i> 10 minute TAT	Lung BILE Status <i>Snap Shot</i> 10 minute TAT
Project Status	Validating at UHN Lung Transplant Group Toronto	Verification of Performance being completed at SQI	Proof of Concept Complete Commercial Scale up in 2020	Product Concept Development this year
Customer Validation	Now	Dec 2019	TBD 2020	Q3 2020

## **Events subsequent to December 31, 2019**

Subsequent to the quarter end, we partnered with UHN to re-apply for the Acute Respiratory Distress Syndrome (ARDS) Genome Canada grant the we did not obtain last year. We believe that with the addition of preliminary clinical data, the application will receive successful review.

In addition, together with UHN and a Chinese-based clinical team, we answered a funding call from the Canadian Institutes of Health Research (CIHR) Canadian 2019-nCoV Rapid Research team for a rapid research response to contribute to the global efforts to contain the COVID-19 outbreak.

This research response is aligned with the efforts of CIHR's international partners, including the World Health Organization (WHO) and the Global Research Collaboration for Infectious Disease Preparedness (GloPID-R).

Finally, and also subsequent to the quarter end, we progressed our TORdx LUNG regulatory efforts by completing an FDA pre-submission meeting and subsequent filing of an FDA application for this test to be accepted into the Breakthrough Medical Device process. For more information from the FDA on this program, [click here](#).

## **Commercial Highlights for the Quarter**

Total revenues for the three months ending December 31, 2019 were \$207,000 compared to \$292,000 for the same period last year. Revenues from kit sales were \$136,000 for the current quarter compared to kit sales of \$103,000 for the last quarter. Revenue from services in the first quarter were \$60,000 compared to \$346,000 in the fourth quarter of 2019. Service revenues were higher in the fourth quarter of 2019 owing to a large contract to develop multiple lung transplant products that are now transitioning to commercial sales. Our lead candidate in this portfolio is in the process of regulatory filing and review by both the FDA and Health Canada. We are selling our TORdx LUNG kits to UHN for research purposes until approved by Health Canada. Should we obtain FDA clearance we will immediately begin marketing and pursuing sales for these products in the US market. We expect to initially target the 20 highest volume lung transplant centers in the US market.

As previously announced, in February of 2019, SQI formed a partnership with UHN's Toronto Lung Transplant Program to develop a multiplexed test to determine the health of donor lungs on EVLP. The biomarkers that form the basis for this test had been the subject of ground-breaking research by UHN scientists for the last five years. The biomarkers though, took too long to run to be useful to surgeons during transplant surgeries. By October 2019, SQI's scientists had developed a highly accurate test that runs in under 45 minutes – instead of the best previous times of 2-3 hours - and surgeons were using our first product, the TORdx LUNG test, in the operating room – as a research use only tool pending regulatory submissions in Canada and the US.

Such a dramatic shortening in testing time enables surgeons to make go-no-go decisions on a lung's viability for transplant *during surgery*. This breakthrough is increasing the number of available lung transplants from 3,000 to 5,000 in Canada and the US – this breakthrough offers the same benefits to transplant groups across the globe.

Due to the ground-breaking potential of the TOR*dx* LUNG test, SQI has asked the Federal Drug Administration in Washington to evaluate the test as a “Breakthrough Medical Device.” This designation shortens the approval process to clearance. This would open the large US market to this test, while erecting barriers to competitors.

While the TOR*dx* LUNG test is the main product being jointly developed by SQI and the Toronto Lung Transplant Program, we also have other lung transplant products in the pipeline.

These products are targeted at: (1) screening recovered donor lungs for serious indications of acidic injury from aspiration which can be treated while on EVLP, (2) a quantitative test expanded from the core TOR*dx* LUNG test to monitor and guide therapeutic treatments of the lung while on EVLP and (3) a Point of Care test to provide a snapshot of lung health, like the TOR*dx* LUNG test but very rapid (<10 minutes) and semi-quantitatively. The key clinical unmet need being addressed with the other tests is to improve the treatment of lungs on EVLP, increase the population of transplantable lungs that can be used, focus EVLP treatment on lungs suffering from aspiration and then clearing them for transplant; ultimately saving lives.

Our partners at UHN have executed a further paradigm shift in procuring, transporting, stabilizing and transferring to the recipients of donor lungs. Lung Transplant (Perfusion) Centers are being set-up across North America with the first established in Toronto and additional centers currently active in Maryland and Florida. 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 2-fold at some centers.

There are currently about 100 key lung transplant centers in the US and 4 in Canada and these centers perform about 75% of world-wide transplants.

The science that enables SQI to create multiplex biomarker test panels for lung transplants is already being advanced in our laboratory to create similar kinds of tests for kidney and liver transplants.

The organ transplant market represents an especially high-value opportunity for SQI. The SQI TOR*dx* LUNG test addresses a large unmet clinical need and a clear opportunity to save lives and improve outcomes for transplant patients and their families. As we progress through the commercialization of SQI's Lung Transplant product pipeline we also expect to develop additional tests that utilize the same biomarkers and that will be used in a similar fashion to assess other organs. Specifically, liver and kidney donor organs that are also perfused outside of the donor prior to transplant. Below is a table that shows the number

of organs transplanted in Canada and the US as a proxy of our total addressable patient market size.

	US			Canada			Total
	2017(a)	2018(a)	2019(e)	2017(a)	2018(a)	2019(e)	2019(e)
Lung	2,070	2,530	2,840	341	357	400	3,240
Liver	6,200	8,250	10,100	430	527	650	10,750
Kidney	16,800	21,200	20,530	3253	3,150	3,050	23,580
<b>Total</b>	<b>25,070</b>	<b>31,980</b>	<b>33,470</b>	<b>4,024</b>	<b>4,034</b>	<b>4,100</b>	<b>37,570</b>

Table 1: Total Lung, Liver and Kidney Transplants US and Canada.

Table 1 shows the number of transplants completed for lungs, kidney and livers in Canada and the US from 2017 through 2019. This is an estimate and does not include all of the organs that do not make it to a recipient. 80% of all donor lungs are currently discarded. Working with UHN, we predict that the number of usable lungs would more than double from its current level of 20% owing to the TORdx-LUNG test aiding surgeons to see that these lungs are actually “good to transplant” (~970 to 1,300 lives saved). Economically, it costs about \$40,000 to prepare a patient prior to surgery, and about \$100,000 to “procure” the lung from the donor and transport it to the recipient. 970 times the \$140,000 cost to this point is sunk cost and is lost – spent whether the transplant goes forward or not. Procurement and pre-surgical preparation costs saved by using these lungs equates to \$135,800,000; this does not include the value to the recipients who may not get a lung transplant in time.

During the quarter ended December 31, 2019, we reached the following milestones:

**1. First commercial Research Use Only (RUO) sales of TORdx LUNG, our first clinical lung transplant test.**

Our product pipeline was focussed on organ transplant and lung health, specifically our TORdx LUNG tests. Our initial multiplexed TORdx LUNG test is in customer evaluation onsite at the UHN Toronto Lung Transplant Program, with two other advanced tests in different stages of product development: our TORdx LUNG+ is a 7-plex test in the final phase of development with customer validation starting in December of 2019; and our Point of Care 2-plex TORdx RAPID test successfully finished the feasibility milestone in October of 2019 and is poised to move to commercialization and production in 2020.

In addition, as we projected last quarter, we are planning to file TORdx LUNG as a Breakthrough Medical Device with the FDA in Q1 of 2020. We are on-track for this important milestone and completed our FDA pre-submission meeting. We also expect to provide more information on our submission requesting designation as a Breakthrough Medical Device.

## **2. We delivered the first Point of Care consumable cartridges and instrument to the UHN Toronto Lung Transplant Program.**

This marks the completion of a significant development milestone that moves this product towards commercialization in our growing lung transplant portfolio. The *TORdx LUNG rapid* is a proprietary point of care test, currently for research-use, co-developed by the Toronto Lung Transplant Program at UHN and SQI Diagnostics. The *TORdx-LUNG rapid* test is a 10-minute test with an intended use of assessing donor lung status.

A second POC test, the *TORdx LUNG bile* test, will be a rapid test used to determine if aspiration of stomach fluids (bile acid) into the donor lung has occurred prior to the lung being put on EVLP. The market for this POC test can be expanded well beyond transplantation. We have completed a technical and market feasibility analysis and have launched the development of this product in fiscal Q2 2020.

Because of our initial success in the research partnership with a world-renowned medical institution, we expect to create an even larger market opportunity. We expect to expand the applicability of the device to other organs beyond lungs and possibly to other diagnostic market segments beyond transplantation. This would include the *RALI-DX* test to aid in the diagnosis of acute lung injury such as Acute Respiratory Distress Syndrome in the hospital setting as we have previously discussed. Current applications could expand to the assessment and triage of patients exposed to or infected by a range of infectious agents such as the Coronavirus COVID-19 that is becoming a global pandemic. In this use model, our *TORdx LUNG+* test could be used to aid in the triage of infected patients to differentiate which patients are more likely to develop serious pulmonary complications from their infections.

## **3. Academic and Professional presentations**

Based on technical and clinical validation work on our *TORdx LUNG* product, two abstracts have been accepted for presentation at the preeminent lung transplantation conference – The International Society for Heart and Lung Transplantation. This conference is to be held in April 2020 in Montreal PQ.

During the quarter, SQI's presentation titled "A Multiple Cytokine Assay to Detect IL-6, IL-8 and IL-10 Using Streptavidin Printed Plates and Multiple Result Reporting" was well-received at the 11<sup>th</sup> Annual Immunogenicity & Bioassay Summit. Conference attendees include target customers in our BioPharma market where we provide test kits and development and testing services in companies' drug development programs.

## **4. Expanding Sales Pipeline**

Our sales funnel continues to expand with many promising new high-value opportunities. These future customers are targeted to add to our recurring revenues and comprise a mix of biopharma customers, contract research organizations, and other diagnostic companies.

Additionally, during the quarter the Company filed Statements of Claim against a former customer in the jurisdictions of Ontario and California, to recover invoiced amounts relating to kit and instrument lease arrangements for approximately \$535,000. These amounts were fully provisioned as of September 30, 2019 and we continue to pursue payment in full.

## **Outlook**

We achieved significant product development milestones in our TOR*dx* LUNG product. Our technology is driving a significant, practical advantage to lung surgeons and our revenue growth is on pace. In 2020 we look to regulatory approvals in Canada and the US. In the period from now to approvals we look forward to selling the TOR*dx* LUNG test as a research use only product to our partner to further both on-going research for new advances in the field as well as to advance the strength of our US FDA Breakthrough device application.

The use model we have developed with our partners involves the use of several TOR*dx* LUNG tests per patient: one or more TOR*dx rapid* tests including one just after recovery of the donor lung, and one or more during EVLP. There are approximately 100 lung transplant centers in the US and 4 in Canada. We will initially target the 20 highest volume transplant centers and then move out to the remaining centers.

We are optimistic that our research partnership with the world-renowned Toronto Lung Transplant Program 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.

We also expect to develop and grow our existing customers in the Direct to Consumer (DTC) market in our CLIA lab business with an expansion of available tests to include rheumatoid arthritis which was approved for use in our CLIA lab subsequent to the quarter end and a general cardiac health screening test that we hope to launch commercially this year.

Again, as with other kinds of SQI tests, the market potential is significant because the clinical need is largely unmet.

Finally, as we continue to grow and enjoy the stability that recurring and more predictable sales brings us, we can turn our attention to creating the efficiencies of scale and lower costs that size conveys to any business. This search for economies will benefit the bottom line in 2020, enabling us to contain our manufacturing costs as we grow our revenues.

## **MANAGEMENT CHANGES**

Ms. Patricia Lie, the Company's Vice President of Finance, resigned effective December 31, 2019 and was subsequently replaced by Ms. Leslie Auld on an interim basis, effective January 15, 2020. Effective February 14, 2020, Mr. Andrew Morris resigned as Chief Executive Officer but remains as a member of the Board of Directors. Also, on February 14, 2020, Dr. Eric Brouwer became Interim Chief Executive Officer while retaining his role as Chief Scientific Officer.

## **CORPORATE FINANCING TRANSACTIONS IN 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.

In addition, on January 31, 2020, the Company announced that it intends to complete a non-brokered private placement (the "Private Placement") of up to units ("Units") of the Company at a price of \$0.09 per Unit for gross proceeds of up to \$4,000,000, subject to regulatory and stock exchange approval. Each Unit will consist of one common share and one common share purchase warrant. Each common share purchase warrant will entitle the holder to purchase one common share at a price of \$0.12 for a period of five years from the date of issuance, subject to accelerated expiry in certain circumstances.

On February 18, 2020, the Company announced that it had completed the first tranche of a non-brokered private placement (the "Private Placement") of 29,629,630 units ("Units") of the Company at a price of \$0.09 per Unit for gross proceeds of approximately \$2.67 million. Each Unit consists of one common share and one common share purchase warrant. Each common share purchase warrant entitles the holder to purchase one common share at a price of \$0.12 for a period of five years from the date of issuance, subject to accelerated expiry in certain circumstances.

All of the Units issued under the first tranche of the Private Placement were purchased by certain insiders of the Company, who are also control persons of the Company. The issuances of Units to such insiders. The Company relied on exemptions from the formal valuation and minority approval requirements on the basis of financial hardship.

The Company intends to complete the second tranche of the Private Placement on or about March 6, 2020 by issuing up to an additional 14,814,814 Units at a price of \$0.09 per Unit, for additional gross proceeds of up to approximately \$1.33 million.

The Private Placement is subject to all necessary regulatory and stock exchange approvals. The securities issued pursuant to the first tranche of the Private Placement will be subject

to a hold period expiring June 15, 2020, in accordance with applicable Canadian securities law.

SQI intends to use the net proceeds of the Private Placement to repay approximately \$1,000,000 of the principal amount of certain 10% secured non-convertible debentures of the Company, plus accrued and unpaid interest thereon, maturing on February 20, 2020, and to fund the Company's product commercialization and manufacturing programs, sales and marketing and for general working capital purposes.

#### *Debenture Extension*

Subsequent to quarter-end, on January 30, 2020, the Company announced the extension of \$1,950,000 principal amount of 10% secured non-convertible debentures of the Company maturing on January 30, 2020 (the "Debentures") for a period of five years (the "Extension"). Interest in the amount of \$195,000 payable by the Company to the holders of the Debentures on the original maturity date was re-advanced to the Company on such date, and such amount increased the principal amount of the Debentures being extended from \$1,950,000 to \$2,145,000 (the "Advance"). Of this amount, an aggregate of \$1,900,000 principal amount of Debentures held by certain insiders, who are also control persons of the Company, was extended, and interest in the amount of \$190,000 was re-advanced to the Company by such insiders.

The maturity dates of the Debentures were extended from January 30, 2020 to January 30, 2025. The Debentures, as amended, continue to be secured by a general security agreement over all of the present and future assets of the Company, including intangibles, and continue to bear interest at a rate of 10% per annum on the principal amount outstanding.

In consideration for the Extension and the Advance, the Company issued 4,116,667 common share purchase warrants ("Warrants"), of which an aggregate of 4,011,111 Warrants were issued to the insiders described above. Each Warrant entitles the holder to purchase one common share at a price of \$0.09 for a period of five years from the date of issuance.

The Extension, the Advance and the issuances of Warrants to insiders (the "Transactions") are considered related party transactions and the Company relied on exemptions from the formal valuation and minority approval requirements in respect of such insider participation on the basis of financial hardship.

The Warrants are subject to a hold period expiring June 1, 2020, in accordance with applicable Canadian securities law. In connection with the Extension with non-insiders of the Company, the Company paid a cash commission of \$3,500 to Regent Capital Partners Inc.

On February 20, 2020, the Company announced that holders of \$286,000 principal amount of 10% secured non-convertible debentures of the Company maturing on February 20, 2020 (the "Debentures") have agreed to extend the maturity date of the Debentures for a period of five years (the "Extension"). Holders of the Debentures have agreed that interest

in the amount of \$28,600 payable by the Company to them on the original maturity date shall be re-advanced to the Company on such date, and such amount shall increase the principal amount of the Debentures being extended from \$286,000 to \$314,600 (the “Advance”).

The Debentures were issued pursuant to a private placement of the Company completed in two tranches on January 30, 2015 and February 20, 2015. The maturity dates of the Debentures will be extended from February 20, 2020 to February 20, 2025. The Debentures, as amended, continue to be secured by a general security agreement over all of the present and future assets of the Company, including intangibles, and continue to bear interest at a rate of 10% per annum on the principal amount outstanding.

In consideration for the Extension and the Advance, the Company has agreed to issue 622,471 common share purchase warrants (“Warrants”). Each Warrant will entitle the holder to purchase one common share at a price of \$0.085 for a period of five years from the date of issuance.

The Extension and the issuance of the Warrants is subject to all necessary regulatory and stock exchange approvals. The Warrants will be subject to a hold period expiring June 21, 2020, in accordance with applicable Canadian securities law. In connection with the Extension, the Company will pay a commission in cash equal to 7% of the principal amount of Debentures being extended to Regent Capital Partners Inc.

## SELECTED FINANCIAL INFORMATION

### First Quarter Commentary

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

	December 31, 2019 (000s)	September 30, 2019 (000s)	June 30, 2019 (000s)	March 31, 2019 (000s)
Revenue	\$ 207	\$ 640	\$ 540	\$ 419
Net Loss	\$ (2,014)	\$ (2,807)	\$ (1,888)	\$ (1,568)
Net Loss Per Share	\$ (0.01)	\$ (0.01)	\$ (0.01)	\$ (0.01)
Weighted Average Shares	232,113	200,477	186,609	167,932
	December 31, 2018 (000s)	September 30, 2018 (000s)	June 30, 2018 (000s)	March 31, 2018 (000s)
Revenue	\$ 292	\$ 563	\$ 220	\$ 176
Net Loss	\$ (1,758)	\$ (1,976)	\$ (2,042)	\$ (1,631)
Net Loss Per Share	\$ (0.01)	\$ (0.01)	\$ (0.02)	\$ (0.01)
Weighted Average Shares	158,407	146,225	134,936	134,936

## Revenues

During the three months ended December 31, 2019, 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 is a break out of our revenue by category.

	Quarter ended December 31, 2019 (000s)		Quarter ended December 31, 2018 (000s)	
Product sales - Kits	\$	136	\$	246
Product sales - Platforms		11		-
Service revenue		60		46
Total revenue	\$	207	\$	292

The deceleration in revenue compared to the prior year's quarter is principally due to the loss of a single customer which the Company stopped shipping kits to in 2019 due to non-payment as further identified in page 9. The Company views this deceleration in revenue as a temporary setback and expects growth to return in the future given the recurring revenue being generated from its current customer base and expanding product portfolio. Significant achievements for the quarter included the first sale of kits used for the TORdx LUNG test which the Company expects to be a stable and growing source of revenue. We continue to develop our commercial pipeline and expect to grow our base of installed platforms and customers who are regularly purchasing kits.

## Net Loss

For the quarter ended December 31, 2020, the Company recorded a net loss of \$2,014,000 (\$0.01 net loss per share) as compared to the net loss of \$1,758,000 (\$0.01 net loss per share) for the quarter ended December 31, 2018. Per share values are based on the weighted average shares outstanding in the relevant period. For the quarter-ended December 31, 2019, there was an average of 232,113 shares outstanding.

The Company continues to develop new products and focus on product commercialization and product delivery.

## Operating Expenses

R&D expenditures, excluding amortization and stock-based compensation, for the three months ended December 31, 2019 were \$1,006,000 compared to \$877,000 for the same period last year. The increase in R&D expenditures for this quarter in fiscal 2020 arose from development work that our scientists concluded for the development of a highly accurate multiplexed test to determine the health of lungs on EVLP in conjunction with our partnership with the Toronto Lung Transplant Program.

Corporate and general expenses, excluding stock-based compensation, totaled \$364,000 for the three months ended December 31, 2019 as compared to \$324,000 for the three months ended December 31, 2018 due to increased staffing and professional fees.

Sales and marketing expenses, excluding stock-based compensation, declined to \$259,000 for the three months ended December 31, 2019 compared to \$325,000 for the three months ended December 31, 2018.

Non-cash, stock-based compensation charges, totaled \$127,000 for the three months ended December 31, 2019 and remained unchanged compared to \$130,000 for the three months ended December 31, 2018.

### **Sources and Uses of Cash**

Management expects further investments in product development and commercialization efforts for its pipeline of custom Ig<sub>plex</sub> consumable kits, new products and platforms, and sales and marketing initiatives through 2020.

The Company has sufficient liquidity to meet its current obligations as they come due. 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. Capital expenditures to increase manufacturing capacity and the purchase of platforms in anticipation of customer demand will impact the Company's cash resources.

Operating activities for the quarter ended December 31, 2019, were financed by cash on hand and from financing initiatives closed during the quarter.

At December 31, 2019, current assets were \$2,493,000 compared to \$2,166,000 at December 31, 2018. As at December 31, 2019, the Company had a (\$2,101,000) working capital deficit compared to a surplus of \$1,230,000 at December 31, 2018. The deficit is primarily due to the reclassification of debentures from a long-term liability to a current liability in the period. See pages 10-12 for the discussion of the private placement and debenture amendments completed after quarter-end.

Cash used in investment activities for the three months ended December 31, 2019 was \$29,000 as compared to \$33,000 for the three months ended December 31, 2018 as the Company is making strategic laboratory equipment purchases and upgrading existing computer infrastructure in order to meet expected customer capacity requirements.

## Outstanding Capital Stock

As at February 24, 2020, there were 261,970,721 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 February 24, 2020:

<b>Number of Warrants (In 000's)</b>	<b>Exercise Price</b>	<b>Maturity</b>
5,330	\$0.64	July 16, 2020
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
28,200	\$0.11	March 1 and 8, 2024
13,429	\$0.17	July 12, 2024
32,300	\$0.13	September 25 and October 22, 2024
4,117	\$0.09	January 30, 2025
29,630	\$0.12	February 18, 2025
622	\$0.09	February 20, 2025
169,789		

The Company had the following stock options outstanding under the Plan at February 24, 2020:

<b>Number of Options (In 000's)</b>	<b>Range of Exercise Prices</b>	<b>Weighted average time to maturity</b>
8,765	\$ 0.09 - 0.25	3.36 years
1,802	\$ 0.26 – 0.39	1.05 years
212	\$ 0.40 – 0.60	0.51 years
10,779		

## 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.

### **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 December 31, 2019;
- (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 December 31, 2019; 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 independent and not involved in the daily operations of the Company. 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.*

*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 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.*

*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 platforms 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.

We are exposed to market risks related to changes in interest rates and foreign currency exchange rates, which could 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 in the success of the Company.