



**SQI DIAGNOSTICS INC.**

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

**September 30, 2019**

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

*This Management's Discussion and Analysis ("MD&A") covers the interim financial statements for the years ended September 30, 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 December 11, 2019.*

*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**

We have made a lot of progress in the on-going evolution of SQI in the 2019 fiscal year.

SQI is 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) Lung Transplant group, the largest lung transplant program in the world. UHN has developed an algorithm and databank, based on multiple biomarkers found in donor lungs that is currently being delivered through SQI’s TORdx™ LUNG test. This resulted in the Toronto Lung Score (TLS) which was showcased at this year’s International Society for Heart and Lung Transplantation (ISHLT) 2019 Annual Meeting and Scientific Sessions. UHN’s Toronto Lung Score (TLS) 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 (EVLV). Follow the link to UHN’s ex vivo perfusion information on the repair of donor organs for lungs, livers and kidneys.

[https://www.uhn.ca/Transplant/Research/Pages/organ\\_repair.aspx](https://www.uhn.ca/Transplant/Research/Pages/organ_repair.aspx)

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 ability to keep and treat a lung on EVLP significantly increases the number of viable lungs that can be transplanted. SQI's TORdx LUNG test amplifies the break-through of EVLP in the health and survival of lung transplant patients. The TORdx LUNG test is a highly sensitive, quantitative test that is performed right in the operating room in under 45 minutes. This replaces qualitative assessments of lungs by surgeons – studies by UHN Lung Transplant Group have shown that this test if applied in the operating room could increase the number of transplantable lungs by ~40%.

### **Commercial Highlights for the Quarter**

Total revenues for the three months ending September 30, 2019 were \$640,000 compared to \$563,000 for the same period last year. Revenues from kit sales were \$103,000 for the current quarter compared to kit sales of \$195,000 for the same period last year. Revenue from services in the fourth quarter, led by our lung transplant partnership at UHN, was \$341,000 compared to \$17,000 in service-based revenue in the fourth quarter in 2018. We also sold one sqidlite platform to UHN delivering \$196,000 in revenue during the quarter.

Over the last year, we achieved consistent growth in our revenues driven by the sales of our consumable kits. Total revenues for the year were \$1,891,000 compared to \$1,335,000 for 2018. This is a growth of 42% year over year.

We have written often about SQI's transition from a research and development company to a commercial, revenue-driven company.

This was a remarkable year because our R&D activities were so quickly commercialized.

Discovery drove development which drove revenues in creating a market where SQI is virtually the only player and that has a very large revenue pipeline worldwide.

Today, 80% of lungs for transplant are discarded after they are removed from the donors. This is either because they are unhealthy or because their viability cannot be determined in time for them to be successfully transplanted into a living patient. Existing viability tests are simply too slow to determine a lung's health in time for it to remain alive and healthy outside the donor's body. The average testing time is three hours.

So, there is an immediate and life-saving need to be able to test in much less time. This is all the more urgent because transplant surgeons are now able to keep recovered lungs alive and healthy outside the body. What the surgeons couldn't do previously is test those lungs in time to be assured that they had a good chance to survive and thrive inside the recipient's body.

But that situation began to change dramatically in 2019 because of a unique partnership between SQI and Toronto's University Health Network.

One of UHN's member hospitals is the Toronto General Hospital, which was ranked one of the Top 10 hospitals in the world. A major reason for Toronto General's high ranking is the ground-breaking work of its Toronto Lung Transplant Program which performs the

most lung transplants of any centre in the world. Additionally, the Surgeon-in-Chief and director of the program, Dr. Shaf Keshavjee, an Officer of the Order of Canada, has attracted worldwide attention for his pioneering research in reconditioning and repairing human donor lungs, making them suitable for transplantation into patients, increasing the number of donor lungs available, and extending the lives of recipient patients.

Donor lungs today can be kept alive outside the body using the Toronto EVLP System for at least four hours. In the future, surgeons expect to extend this time to as many as two days. During this time, recovered lungs can be treated for a variety of pre-existing conditions to optimize their health before the lung is transplanted, both improving transplant outcomes and increasing the number of viable donor organs that can be transplanted. This extended time also vastly increases the time and distance possible to find a suitable lung recipient. This markedly improves the outcomes for recipients, shortens their stay in the ICU and dramatically reduces costs.

Close to \$100 million in procurement and pre-operative costs in Canada and the US can be saved for a lung that would have otherwise been discarded if the EVLP treated lungs can be tested to be viable.

This is all very promising. But being assured that a donor lung is healthy requires a test that takes three hours to complete. During that time, the *ex vivo* lung may wither and cease to function. What's more, surgeons still don't have the precision they need to make a truly informed decision about the lung's health.

This is all changing – because of the quality of SQI's research and development and the global reputation of its UHN partners.

In February of 2019, SQI formed a partnership with the Toronto Lung Transplant Program to develop a multiplexed test to determine the health of 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, SQI's scientists had developed a highly accurate test that runs in 45 mins 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 for the TORdx LUNG test SQI has requested the evaluation of the test by the Federal Drug Administration in Washington 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, there are other lung transplant products in the pipeline. These 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 EVLP treatments and aiding any required adjustments 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 unmet need being addressed with the other tests is to improve 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 initiated a further paradigm shift in the procurement, transport, stabilization and transfer 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.

EVLP has nearly doubled the growth rate of lung transplants in centers where it is used.

There are currently 110 key lung transplant centers in the US and 5 in Canada and these centers perform about 75% of world-wide transplants.

We have made great technical progress with our UHN partners. We signed our 3-product development agreement in February 2019. Today, we have TOR*dx* LUNG being used in the Toronto General operating room in Research Use Only validation case studies; we also have the TOR*dx* LUNG + expanded panel targeting perfusion therapy end-points nearing transfer to UHN for use in the hospital setting; and, the TOR*dx* RAPID which is a multiplexed proof of concept test to be used as a snapshot test to evaluate donor lungs that is currently working as a 10 minute, semi quantitative test that has passed our proof of principle stage gate.

The science that enables SQI to create multi-plex biomarkers 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 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
Total	25,070	34,980	33,470	4,024	4,034	4,100	37,570

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

The Lung transplant market has been growing at about 30% per year for the last 3 years. This growth has largely been influenced by the advances in ex vivo lung perfusion that has been used to treat lungs and converted them from being rejected for transplant, to being accepted. TORdx LUNG plus the TLS are the next wave in the growth of the lung transplant market by testing lungs and accepting the condition of a lung that would have previously been assessed as non-viable and rejected. SQI is making a huge impact in the clinical evolution of lung transplant diagnostics and influencing the growth of the market – as the number of lungs transplanted grows this means that a recipient gets a lung that he may have otherwise not, or never received.

Table 1 shows the number of transplants completed for lungs, kidney and livers in Canada and the US from 2017 through 2019 (estimated) – this does not include all of the organs that do not make it to a donor. 80% of all donor lungs are currently discarded. Working with UHN, we predict 30 to 40% of discarded lungs would be used owing to TORdx-Lung and TLS 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 \$97,000,000; this does not include the value to the recipients who may not get a lung transplant in time.

During the year ended September 30, 2019, we reached the following milestones:

**1. Completed development 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 Toronto Lung Transplant Centre, 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 moving to commercialization and production in 2020.

In addition, we are planning to file TORdx LUNG as a Breakthrough Medical Device with the FDA in Q1 of 2020; we have filed our initial request to the FDA requesting a pre-submission meeting that we expect to have completed by January 2020.

## **2. We deployed the first sqidlite instrument to UHN, Toronto General Hospital's Lung Transplant Group.**

The TORdx LUNG is a proprietary test, currently for research-use, co-developed by the Toronto Lung Transplant Program at UHN and SQI Diagnostics. The Toronto Lung Score was developed based on an algorithm developed by UHN. The algorithm uses the levels of biomarkers from donor lungs and the historic decision to transplant matched to recipient outcomes to predict how a current donor lung will perform if transplanted. The TORdx-LUNG test is used to generate the score and will be used by surgeons to make go-no-go decisions as well as to make post surgical treatment plans. The sqidlite and TORdx-LUNG test is being used in the operating room during lung transplantation procedures along side other diagnostic tools to compile data for regulatory submissions and other research to promote the adoption of the TLS across the world.

In Canada today, it can cost up to \$750,000 to perform a lung transplant and to care for the patient after their surgery. The cost in the USA can be much greater than this. The SQI TORdx-LUNG used to deliver the TLS score is a major factor in reducing these costs.

During the fourth quarter we also completed a significant amount of work on the second product in the TORdx LUNG pipeline, the TORdx-LUNG+ test. This is an expanded panel that aids in the “go-no-go” decision for a lung on EVLP and also provides quantitative measures of the effectiveness of a variety of treatments of the lung on EVLP. We are targeting a completion of SQI validation and transfer to UHN of this product in December 2019.

Alongside the TORdx LUNG tests we are developing a series of point-of-care (POC) tests focussed on lung transplant diagnostics and that can be extended to lung health in other markets. For SQI, the market for a high-quality POC testing device for lung transplants would significantly expand its transplant market because a POC test could be used to screen donor lungs at any hospital that performs lung transplants and could be used for post surgical monitoring. In further discussions with our transplant partners, we determined to co-develop a second POC test with them. This second POC test, the TORdx LUNG *bile* test, will be a rapid test used to determine if aspiration has occurred into the donor lung prior to 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 plan to launch the development of this product in Q1 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 in the hospital setting as we have previously discussed.

### **3. CLIA Lab Buffalo running DTC imaware samples.**

Last quarter we were notified by our CLIA lab partner that the New York State Department of Health has given us the green light so patient testing can begin for our imaware™ partner's Celiac test.

This quarter we began earning commercial revenue from our CLIA lab. We also completed product validation to allow us to obtain a similar CLIA clearance to run our imaware rheumatoid arthritis tests. This test is targeted at early indications of developing rheumatoid arthritis in consumers concerned about the disease. Running our customers' tests in our CLIA facility will deliver incremental revenue and gross margin per test in addition to the kits revenue we were previously generating.

### **4. Cardiac Test**

During the year the Company worked very closely with one customer to improve their product specifications and address performance questions. The Company was eager to assist with further development of this product to advance this customer's regulatory and commercial plans. It is the Company's position that all product shipped to the customer met existing product performance criteria. The customer had agreed to pay outstanding amounts but has failed to follow through on their financial obligations. The Company has stopped shipping product to this customer until their account is paid in full. The Company has engaged US legal counsel and is actively pursuing collection.

### **5. Expanding Sales Pipeline**

In the quarter we received samples to complete the service portion of one of our on-going biopharma development projects. After delivering to them the final project report subsequent to the quarter end, we foresee additional service revenue from this customer owing to the positive response from the development and testing program. Subsequent to the quarter, we have also been negotiating terms for the sale of the trial sqid-X system to our CRO customer target that has been discussed in prior disclosures. This sale would also come with one or more new projects. During the quarter, our DNA test customer continued to buy test kits at sustained but low volume and indications from them are that their commercialization plans for this product have matured and they report to us that they will be increasing their demand for these products.

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.

## **Outlook**

We achieved significant product development milestones in our TORdx 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 TORdx 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 TORdx LUNG tests per patient, one or more TORdx 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 5 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 POC 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 DTC market in our CLIA lab and biopharma projects.

Again, as with other kinds of SQI tests, the market potential is significant because the 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 ultimately benefit the bottom line in 2020, enabling us to contain our manufacturing costs as we grow our revenues.

## **CORPORATE FINANCING TRANSACTIONS**

On December 20, 2017, the Company completed a non-brokered private placement of an aggregate of 31,061,300 units of the Company at \$0.15 per unit for gross proceeds of \$4,659,000. Each unit comprises one common share of the Company and one common share purchase warrant. Each warrant is exercisable at a price of \$0.20 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. In connection with the private placement, the Company paid a finder's fee of \$75,000 and issued 463,260 compensation warrants exercisable for 36 months from the closing of the private placement. Each compensation warrant is exercisable into one common share at a price of \$0.20.

On May 1, 2018, 5,126,044 warrants issued in May 2013 in connection with a private placement with an exercise price of \$1.10 expired unexercised.

On July 10, 2018 Company received approval to extend the expiry of 5,330,000 warrants from July 16, 2018 to July 16, 2020. The warrants were issued in connection with a private placement in July of 2015. All other terms of the warrants remain unchanged.

On August 17, 2018 and August 24, 2018, the Company completed a non-brokered private placement of an aggregate of 23,471,101 units of the Company at \$0.15 per unit for gross proceeds of \$3,521,000. Each unit comprises one common share of the Company and one common share purchase warrant. Each warrant is exercisable at a price of \$0.20 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.

On December 6, 2018, the Company received approval to extend the expiry of 7,630,945 warrants that were issued in connection with a private placement in December of 2015. 7,480,945 warrants that were to expire on December 15, 2018 have been extended to December 15, 2020, and 150,000 warrants that were to expire on December 22, 2018 have been extended to December 22, 2020. All other terms of the warrants remain unchanged. Accordingly, \$88,000 was recorded in warrant capital with a corresponding reduction in contributed surplus in fiscal 2019.

On January 26, 2019 2,965,000 warrants issued in connection with a private placement in January of 2014 with an exercise price of \$0.64 and an expiry date of January 26, 2019 expired unexercised.

On March 1, 2019 and March 8, 2019, the Company completed a non-brokered private placement of an aggregate of 28,200,005 units of the Company at \$0.08 per unit for gross proceeds of \$2,256,000. Each unit comprises one common share of the Company and one common share purchase warrant. Each warrant is exercisable at a price of \$0.11 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.

On April 10, 2019, 8,400,000 warrants issued in connection with a public offering in April

of 2014 with an exercise price of \$0.64 and an expiry date of April 10, 2019 expired unexercised.

On June 6, 2019, 5,000 warrants were exercised for gross proceeds of \$1,000. The warrants were issued in connection with a private placement in August of 2018 with an exercise price of \$0.20.

On July 12, 2019, the Company completed a non-brokered private placement of an aggregate of 13,428,849 units of the Company at \$0.13 per unit for gross proceeds of \$1,746,000. Each unit comprises one common share of the Company and one common share purchase warrant. Each warrant is exercisable at a price of \$0.17 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.

On September 25, 2019, the Company completed a non-brokered private placement of an aggregate of 31,300,000 units of the Company at \$0.10 per unit for gross proceeds of \$3,130,000. 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.

Subsequent to year end, on October 22, 2019, the Company closed a second tranche of the non-brokered private placement of an aggregate of 1,000,000 units for gross proceeds of \$100,000.

## SELECTED FINANCIAL INFORMATION

The table below summarizes annual financial information for the fiscal years ended September 30, 2019 and 2018.

	Year ended September 30, 2019 (000s)	Year ended September 30, 2018 (000s)
Revenue	\$ 1,891	\$ 1,335
Net Loss	\$ (8,021)	\$ (7,437)
Net Loss Per Share	\$ (0.04)	\$ (0.06)
Weighted Average Shares	178,391	130,974

### Revenues

Revenue for the year ended September 30, 2019 was \$1,891,000 versus \$1,335,000 for the year ended September 30, 2018. This corresponds to about a 40% increase in revenues and more significantly is driven by significant commercial progress. The table below is a break out of our revenue by category.

	Year ended September 30, 2019 (000s)	Year ended September 30, 2018 (000s)
Product sales - Kits	\$ 949	\$ 454
Product sales - Platforms	196	606
Service revenue	746	275
Total revenue	\$ 1,891	\$ 1,335

The table above shows a significant increase in both kit sales and service revenue. The increase in kit sales is as a result of three projects with two customers in the commercial phase in 2019. These projects became commercial during fiscal 2018 thus 2019 reflects a full year of growing commercial traction with these customers. The growth in service revenues is principally a result of a development project undertaken in fiscal 2019 with University Health Network (UHN) for the lung transplant tests discussed above. These development projects are expected to create significant revenue potential as discussed earlier in this document. The Company sold one platform in fiscal 2019 as compared to four in fiscal 2018 resulting in the decline in platform revenue. As mentioned previously, platform revenues will be lumpy and result in revenue fluctuations as customers are added

to the commercial pipeline. 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**

The net loss for the year ended September 30, 2019 was \$8,021,000 (\$0.04 net loss per share) as compared to \$7,437,000 (\$0.06 net loss per share) for the year ended September 30, 2018. The net loss for the year ended September 30, 2019 is consistent with the loss for the year ended September 30, 2018. Per share values are based on the weighted average shares outstanding in the relevant period. For the year ended September 30, 2019, there was an average of 178,391,000 shares outstanding.

The increase in revenues was offset by increases in costs related to scaling up commercialization activities including producing at larger volumes and increasing manufacturing and marketing capacity.

### **Operating Expenses**

Research and development (“R&D”) costs, excluding amortization and stock-based compensation were \$4,212,000 for the year ending September 30, 2019. This compares to \$3,717,000 for the year ending September 30, 2018. In fiscal 2019, R&D efforts were focused on development work for one significant customer project; the development of assays to assessing the suitability of lungs for transplant and a companion point of care test. R&D activities were also focused on changes to existing products to improve product performance and meet additional customer design change requests. In addition, activities were undertaken to improve processes, streamline activities and facilitate manufacturing at larger volumes.

Corporate and general expenses include salaries and related expenses (including benefits and payroll taxes); general and administrative expenses; and professional consulting costs (legal, accounting, Board of Directors compensation, recruiting, administrative contractor, and investor relations).

Corporate and general expenses excluding stock-based compensation totalled \$1,635,000 for the year ended September 30, 2019 and \$1,589,000 for the year ended September 30, 2018. Corporate and general expenses were higher over the comparable periods due to increased rent at the company head office and increased personnel costs. These increased costs were partially offset by decreases in professional fees related to recruiting and legal fees.

As discussed above the Company has stopped shipping product to one customer until their account is paid in full. The Company has engaged US legal counsel and is actively pursuing collection. The Company believed it was prudent to record a provision of \$534,000 against the full balance of this receivable.

Sales and marketing expenses were primarily related to sales and marketing staff compensation and to travel related to selling activities. Sales and marketing expenses, excluding stock-based compensation, totalled \$1,174,000 for the year ended September

30, 2019 compared to \$1,145,000 for the year ended September 30, 2018. Sales and marketing costs were consistent year over year.

## Fourth Quarter Commentary

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

	September 30, 2019 (000s)	June 30, 2019 (000s)	March 31, 2019 (000s)	December 31, 2018 (000s)
Revenue	\$ 640	\$ 540	\$ 419	\$ 292
Net Loss	\$ (2,807)	\$ (1,888)	\$ (1,568)	\$ (1,758)
Net Loss Per Share	\$ (0.01)	\$ (0.01)	\$ (0.01)	\$ (0.01)
Weighted Average Shares	200,477	186,609	167,932	158,407
	September 30, 2018 (000s)	June 30, 2018 (000s)	March 31, 2018 (000s)	December 31, 2017 (000s)
Revenue	\$ 563	\$ 220	\$ 176	\$ 376
Net Loss	\$ (1,976)	\$ (2,042)	\$ (1,631)	\$ (1,788)
Net Loss Per Share	\$ (0.01)	\$ (0.02)	\$ (0.01)	\$ (0.02)
Weighted Average Shares	146,225	134,936	134,936	107,926

## Revenues

Revenues for the three months ended September 30, 2019 increased by approximately 14% as compared to the same quarter in fiscal 2018. Revenue was generated from the sale of custom kits, platforms, as well as service revenue. The table below provides a breakout of revenue by category for the three-month periods:

	Three months ended September 30, 2019 (000s)	Three months ended September 30, 2018 (000s)
Product sales - Kits	\$ 103	\$ 195
Product sales - Platforms	196	351
Service revenue	341	17
Total revenue	\$ 640	\$ 563

Recurring kit sales decreased approximately 47% from the fourth quarter of fiscal 2018. This is a result of decreased sales to one of our diagnostic customers as discussed above. While it is possible we will improve our position with this customer, their inability to pay

for product has caused us to stop selling to them; it is possible that we will not sell to them in the future. The potential loss of this customer is expected to be overcome by revenue and market expansion into the US for our Lung Health portfolios.

Platform revenue is lower in the last quarter of fiscal 2019 as compared to the same quarter in fiscal 2018. Two platforms were delivered and installed at a customer site in the fourth quarter of fiscal 2018; one platform was installed at our lung transplantation customer to enable validation and adoption of the lung transplantation assay in 2019. Service revenues are significantly higher for the three months ended September 30, 2019 as compared to the same quarter in 2018. This is mainly attributable to revenue earned on the development of the lung transplantation tests.

### **Net Loss**

For the three months ended September 30, 2019 the Company recorded a net loss of \$2,807,000 (\$0.01 net loss per share) as compared to the net loss of \$1,976,000 (\$0.01 net loss per share) for the three months ended September 30, 2018. Per share values are based on the weighted average shares outstanding in the relevant period. For the quarter ended September 30, 2019, there was an average of 200,477,000 shares outstanding.

The net loss was higher for the three months ended September 30, 2019 as compared to the three months ended September 30, 2018. Increases in revenue in the fourth quarter were offset by an increase in other expenses. Fourth quarter expenses were impacted by the timing of corporate bonuses and consulting costs for the lung transplant point-of-care device and the accounts receivable provision discussed earlier.

### **Operating Expenses**

R&D expenditures, excluding amortization and stock-based compensation, for the three months ended September 30, 2019 were \$1,495,000 compared to \$870,000 for the same period last year. The increase in R&D expenditures for the three-month periods is a result of increased laboratory costs. These costs relate to consulting fees paid for the design and development of a point-of-care companion test for the lung transplantation assay. The increase in R&D costs is also a result of the timing of bonus payments and increased salary costs as the full year impact of personnel hired in 2018 is reflected in the 2019 expenses.

Corporate and general expenses, excluding stock-based compensation, totaled \$548,000 for the three months ended September 30, 2019. This compares to \$461,000 for the three months ended September 30, 2018. The increase in the third quarter was the result of higher rent at the Company's head office location and the timing of corporate bonuses.

Sales and marketing expenses were primarily related to sales and marketing consultant fees and to travel related to selling activities in the quarter. Sales and marketing expenses, excluding stock-based compensation, totaled \$210,000 for the three months ended September 30, 2019 compared to \$300,000 for the three months ended September 30, 2018. Sales and marketing expenses were lower for the three months ended September 30, 2019 compared to the same periods in the previous year. The lower platform and kit

sales in last quarter of fiscal 2019 as compared to the same period in fiscal 2018 resulted in lower commission payouts and reduced travel for platform installation and training.

Non-cash, stock-based compensation charges, totaled \$164,000 for the three months ended September 30, 2019 (Fiscal 2019 - \$593,000) compared to \$129,000 for the three months ended September 30, 2018 (Fiscal 2018 - \$405,000). The related stock option issuances are detailed later in this document.

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

Management expects further investments in product development and commercialization efforts for its pipeline of custom Ig\_plex consumable kits, new products and platforms, and sales and marketing initiatives through 2019.

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 year ended September 30, 2019, were financed by cash on hand and from financing initiatives closed during the year.

At September 30, 2019, current assets were \$4,494,000 compared to \$3,758,000 at September 30, 2018. As at September 30, 2019, the Company had a \$217,000 working capital deficit compared to a surplus of \$2,691,000 at September 30, 2018. The deficit is mainly due to the debentures being reported as current in the current quarter.

Cash used in investment activities for the three months ended September 30, 2019 was \$29,000 (fiscal 2019 - \$200,000) compared to \$49,000 for the three months ended September 30, 2018 (fiscal 2018 - \$297,000). The Company is making strategic laboratory equipment purchases and upgrading existing computer infrastructure in order to meet customer capacity requirements.

### **Outstanding Capital Stock**

As at December 11, 2019, there were 232,341,091 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 December 11, 2019:

<b>Number of Warrants</b>	<b>Exercise Price</b>	<b>Maturity</b>
5,330	\$0.64	July 16, 2020
3,560	\$0.59	January 30, 2020 and February 20, 2020
7,631	\$0.52	December 15 and 21, 2020
22,970	\$0.21	March 10, 2022
463	\$0.20	December 20, 2020
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, 2024
<b>168,410</b>		

The Company had the following stock options outstanding under the Plan at December 11, 2019:

<b>Number of Options</b>	<b>Range of Exercise Prices</b>	<b>Weighted average time to maturity</b>
9,478	\$ 0.09 - 0.25	3.75 years
1,957	\$ 0.26 – 0.39	1.45 years
332	\$ 0.40 – 0.60	0.93 years
<b>11,767</b>		

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

The Company has no off-balance sheet arrangements.

The Company’s financial statements are prepared in accordance with International Financial Reporting Standards (“IFRS”).

### **CRITICAL ACCOUNTING POLICIES AND SIGNIFICANT ESTIMATES**

The significant accounting policies that management believes are the most critical in fully understanding and evaluating the reported financial results include the following:

#### **Revenue Recognition**

The Company generates revenue from the sale of goods, and by services rendered. Revenue is measured based on the consideration specified in a contract with a customer. Revenue is recognized as performance obligations are satisfied and the Company transfers control over a product to a customer. With respect to incremental costs such as sales

commissions incurred in obtaining a contract, the Company has elected to apply the practical expedient to expense these costs when incurred as the term of the Company's contracts are typically one year or less.

#### *Product Sales*

Product sales consist of contracts to provide customers with consumable test kits and diagnostic platforms. The Company generally considers these types of contracts to contain a single performance obligation satisfied at a point in time. The following factors are considered in determining when to recognize revenue:

- whether the Company has a present right to payment
- whether the buyer has legal title to the asset, if physical possession of the asset has transferred to the buyer and whether the buyer has the significant risks and rewards of ownership
- whether the buyer has accepted the asset

Generally, the buyer obtains control at the time goods have been delivered. However, platform contracts typically include installation and training services to be performed by the Company in addition to delivering the finished platform. Since these performance obligations are not considered distinct, revenue is recognized once all the associated services have been completed.

#### *Services Rendered*

Service contracts are either executed separately or bundled together with platform sale contracts. Where these contracts are bundled together, they are regarded as separate performance obligations, as each of the promises are capable of being distinct and are separately identifiable. Accordingly, a portion of the transaction price is allocated to each performance obligation relative to standalone selling prices.

A service contract can include research and development services, maintenance services, training, onsite support, field service, remote support, and consulting services. The Company generally considers service contracts to contain one performance obligation which is satisfied over time. However, for customer contracts that contain multiple performance obligations, each element is treated separately for revenue recognition purposes with the total transaction price allocated to each obligation based on its relative stand-alone selling price. Revenue is then recognized for each obligation based on the following methods:

- For research and development contracts, the stage of completion is measured through appraisals and evaluations of results achieved in relation to preestablished milestones.
- The stage of completion of fixed-price contracts to provide an indeterminable number of services over a specified period is measured based on contract term elapsed as a percentage of the full contract term.
- The stage of completion of time and material contracts is measured using the right to invoice practical expedient – revenue is recognized at the contractual rates as labour hours are delivered and direct expenses are incurred.

### *Revenue Related Assets and Liabilities*

#### Trade Receivables:

A trade receivable represents the Company's right to an amount of consideration that is unconditional (i.e., only the passage of time is required before payment of the consideration is due).

#### Contract Liabilities:

Contract liabilities represents the obligation to transfer goods and services to a customer for which the Company has received consideration from the customer. Revenue is recognized when the Company performs under the contract.

### **Intangible Assets**

Patents and trademarks comprise costs, including professional fees, incurred in connection with the creation and filing of patents and registration of trademarks related to the Company's core technology and trademarks. The costs relating to initial patent and trademark fees are deferred and amortized over 10 years on a straight-line basis. Patents and trademarks are recorded net of impairment losses, if any.

Research costs are charged to operations in the period in which they are incurred. Development costs are deferred if they meet the criteria for deferral under IFRS where; the product or process is clearly defined and the costs attributable thereto can be identified, the technical feasibility has been established, management has indicated its intention to produce and market the product, the future market is clearly defined, adequate resources are available, and recovery of development costs can reasonably be regarded as assured and are expected to provide future benefits with reasonable certainty. Deferral criteria have not been met, and accordingly, all development costs have been expensed in the year.

### **Stock-Based Compensation and Other Stock-Based Payments**

The Company offers a share option plan for its directors, officers, and employees. The fair value of stock-based payment awards granted is recognized as an expense with a corresponding increase in contributed surplus. The Company grants stock options with multiple vesting periods, with each vesting period being treated as a separate tranche and considered a separate grant for the calculation of fair value. Fair value is calculated using the Black-Scholes option pricing model and the resulting fair value is amortized over the vesting period of the respective tranches. In addition, stock-based compensation expense recognized reflects estimates of award forfeitures with any change in estimate thereof reflected in the period of the change. Consideration received upon the exercise of stock options is credited to capital stock at which time the related contributed surplus is transferred to capital stock.

### **Leases**

Leases for which the Company assumes substantially all the risks and rewards of ownership are classified as finance leases, and the Company is the lessee. Upon initial recognition, the leased asset is measured at an amount equal to the lower of its fair value and the present value of the minimum lease payments. Subsequent to initial recognition,

the asset is accounted for in accordance with the accounting policy applicable to that asset. Lease payments are apportioned between finance charges and reduction of the lease liability so as to achieve a constant rate of interest on the remaining balance of the liability. Finance charges are recognized in in the Statement of Loss and Comprehensive Loss.

Leases for which the Company transfers substantially all the risks and rewards of ownership are classified as finance leases, and the Company is a lessor. Upon initial recognition, a receivable is recorded for the leased asset, at an amount equal to the net investment in the lease. The net investment in the lease is the minimum lease payments receivable by the Company and any unguaranteed residual value accruing to the Company, all discounted at the interest rate implicit in the lease. Subsequent to initial recognition, the lease payments received are apportioned between reduction of the receivable and finance income based on the effective interest rate method using the rate implicit in the lease. The sales revenue recognized at the commencement of the lease term is the fair value of the asset, or, if lower, the present value of the minimum lease payments accruing to the lessor, computed at a market rate of interest. The cost of sale recognized at the commencement of the lease term is the cost, or carrying amount if different, of the leased property less the present value of the unguaranteed residual value.

Leases for which the Company does not transfer substantially all the risks and rewards of ownership are classified as operating leases. Payments are recorded as expenses as they are incurred.

### **Income Taxes**

The Company follows the asset and liability method of accounting for income taxes. Under this method, deferred income tax assets and liabilities are determined based on temporary differences between financial reporting and tax bases of assets and liabilities, as well as for the benefit of losses available to be carried forward to future years for tax purposes. Deferred income tax assets and liabilities are measured using enacted or substantively enacted tax rates and laws that will be in effect when the differences are expected to reverse. Deferred tax assets for unused tax losses, investment tax credits (“ITCs”) and deductible temporary differences are recorded in the financial statements to the extent that it is probable that future taxable profits will be available against which they can be utilized.

### **Critical Accounting Estimates and Judgments**

The preparation of financial statements in conformity with IFRS requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amount of revenue and expenses during the period. Actual results could differ from those estimates. The following judgments and estimates are those deemed by management to be material to the Company’s consolidated financial statements.

(i) Inventory

The Company estimates the net realizable values of inventory, taking into account the most reliable evidence available at each reporting date. The future realization of inventory may be affected by future technology or other market-driven changes that may reduce future selling prices.

(ii) Revenue

Some of the Company's service contracts are complex and include promises to transfer multiple products and services. For these complex arrangements, each good or service is evaluated to determine whether it represents a distinct performance obligation. Measurement and recognition of revenue requires the Company to make estimates of transaction price, stand-alone selling prices and progress towards complete satisfaction of performance obligations.

(iii) Property and Equipment and Patents and Trademarks

Measurement of property and equipment and patents and trademarks involves the use of estimates for determining the useful lives for amortization of property and equipment and patents and trademarks. Among other factors, these judgments are based on industry standards, manufacturer's guidelines and company-specific history and experience.

(iv) Impairment of non-financial assets

Assessment of impairment is based on management's judgment of whether there are sufficient internal and external factors that would indicate that an asset, or an asset of a CGU, is impaired. The assessment of these factors, as well as the determination of a CGU, is based on management's judgment. Management has assessed SQI Diagnostics Inc. as one CGU and considers factors such as whether an active market exists for the output produced by the assets as well as other market factors to determine if an asset is impaired.

(v) Stock-based compensation and warrants

The Company uses an option pricing model to determine the fair value of stock-based compensation and warrants. Inputs to the model are subject to various estimates relating to volatility, interest rate and expected life of the instrument. Fair value inputs are subject to market factors as well as internal estimates. The Company considers historic trends together with any new information to determine the best estimate of fair value at the date of grant.

Separate from the fair value calculation, the Company is required to estimate the expected forfeiture rate of stock-based compensation.

(vi) Deferred tax assets

Deferred tax assets and liabilities contain estimates about the nature and timing of future deductible temporary differences as well as the future tax rates that will apply to those differences. Changes in tax laws and rates as well as changes to the expected timing of reversals may have a significant impact on deferred tax assets and liabilities. Currently, the Company has deductible temporary differences which would create a deferred tax asset. Deferred tax assets are recognized for all deductible temporary differences to the extent that it is probable that future taxable profit will be available against which the deductible temporary differences can be utilized. Management judgment is required to determine the amount of deferred tax assets that can be recognized, based upon the likely timing and the level of future taxable profits together with future tax planning strategies. To date, the Company has determined that none of its deferred tax assets should be recognized. The generation of future taxable income could result in the recognition of some or a portion or all of the remaining benefits, which could result in an improvement in the Company's results of operations through the recovery of future income taxes.

(vii) Secured debentures

The Company uses valuation techniques that include inputs that are not based on observable market data to estimate the value of the secured debentures and the related warrants.

## RECENT ACCOUNTING PRONOUNCEMENTS

### (a) Adoption of new accounting standards

On October 1, 2018, the Company adopted IFRS 9 "Financial Instruments" which replaced IAS 39 "Financial Instruments: Recognition and Measurement". IFRS 9 uses a single approach to determine whether a financial asset is measured at amortized cost or fair value, replacing the multiple rules in IAS 39. The approach in IFRS 9 is based on how an entity manages its financial instruments in the context of its business model and the contractual cash flow characteristics of the financial assets. Most of the requirements in IAS 39 for classification and measurement of financial liabilities were carried forward unchanged to IFRS 9. The new standard also requires a single impairment method to be used, replacing the multiple impairment methods in IAS 39. IFRS 9 also includes requirements relating to a new hedge accounting model, which represents a substantial overhaul of hedge accounting which will allow entities to better reflect their risk management activities in the financial statements. The adoption of IFRS 9 did not have a material impact on the consolidated financial statements.

	Original classification (measurement) IAS 39	New Classification and measurement IFRS 9
Cash	Loans and receivable (amortized cost)	Amortized cost
Accounts receivable	Loans and receivable (amortized cost)	Amortized cost
Accounts payable and accrued liabilities	Other financial liabilities (amortized cost)	Amortized cost

On October 1, 2018, the Company adopted IFRS 15, Revenue from Contracts with Customers, which superseded existing standards and interpretations including IAS 18, Revenue, and IFRIC 13, Customer Loyalty Programmes. IFRS 15 introduces a single model for recognizing revenue from contracts with customers with the exception of certain contracts under other IFRSs such as IAS 17, Leases. The standard requires revenue to be recognized in a manner that depicts the transfer of promised goods or services to a customer and at an amount that reflects the expected consideration receivable in exchange for transferring those goods or services. This is achieved by applying the following five steps:

1. Identify the contract with a customer;
2. Identify the performance obligations in the contract;
3. Determine the transaction price;
4. Allocate the transaction price to the performance obligations in the contract; and
5. Recognize revenue when (or as) the entity satisfies a performance obligation.

IFRS 15 also provides guidance relating to the treatment of contract acquisition and contract fulfillment costs. The Company adopted IFRS 15 using the modified retrospective transition method, with the cumulative effect of initially applying the standard recognized as an adjustment to opening retained earnings at the date of initial adoption. The adoption of IFRS 15 did not have a material impact on the consolidated financial statements.

#### **(b) New Accounting Standards and Interpretations not yet adopted**

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 has not yet completed its evaluations of the effect of adopting the above standards and amendment and the impact it may have on its consolidated financial statements.

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

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

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

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

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

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

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

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

We have limited commercial history and have incurred significant losses in each fiscal year since inception. As of September 30, 2019, we had an accumulated deficit of \$94.8 million. These losses have resulted principally from costs incurred in our research and development programs and from our sales, general and administrative expenses. Because of the numerous risks and uncertainties associated with our commercialization efforts and future product development, there is risk associated with the timing of achieving profitability, and we may never become profitable.

### ***Market Competition***

The markets for our products are characterized by rapidly changing technology, evolving industry standards, changes in customer needs, emerging competition, new product

introductions and strong price competition. We compete with both established and development stage companies, universities, research institutions, governmental agencies and healthcare providers that design, manufacture and market similar diagnostic products, many of whom have significantly greater financial and human resources, research, development and marketing capabilities, intellectual property and name recognition than the Company.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We are in the early stages of commercializing, selling, distributing, and marketing of products, in which we have limited experience. We intend to market, sell and distribute

our products directly through our own sales force in North America, Europe and elsewhere. Our future sales will depend in large part on our ability to develop and substantially expand our direct sales force and to increase the scope of our marketing efforts.

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

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

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

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

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

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

### ***Key Personnel***

Our performance depends substantially upon the performance of our senior management and key scientific and technical personnel, including our Chief Executive Officer, Andrew Morris, and our Chief Scientific Officer, Dr. Eric Brouwer. If we are unable to attract and retain skilled and experienced personnel, or if we lose the services of any member of our

senior management or our key scientific or technical staff, it could have a material adverse effect on our business, financial condition and results of operations.

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

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

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

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

In manufacturing our products, we depend upon third parties for the supply of various components. Many of these components require a significant degree of technical expertise to produce. If our suppliers fail to produce components to specification, or if defective materials or workmanship are used in the manufacturing process, the reliability and performance of our products will be compromised. The occurrence of any one or more of the foregoing could negatively affect our business, financial condition and results of operations.

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

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

## **Risks Related to Intellectual Property**

### ***Intellectual Property Protection***

Our commercial success depends, in part, upon our ability to protect our intellectual property and proprietary technologies. We rely on patent protection, where appropriate and available, as well as a combination of copyright, trade secret and trademark laws, and

nondisclosure, confidentiality and other contractual restrictions to protect our proprietary technology. However, these legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. Our pending Canadian, U.S. and foreign patent applications may not issue as patents or may not issue in a form that will be sufficient to protect our proprietary technology and gain or keep our competitive advantage.

We may be involved in litigation or other proceedings to protect or enforce our patents and proprietary rights, to determine the scope, coverage and validity of others' proprietary rights, or to defend against third party claims of intellectual property infringement, and the cost to the Company of any litigation or other proceedings, even if resolved in our favour, could be substantial.

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

### ***Volatility of Share Price***

Securities markets have a high level of price and volume volatility, and the market price of securities of many companies have experienced wide fluctuations in price which have not necessarily been related to the operating performance, underlying asset values or prospects of such companies. As a result, the market price of our common shares at any given point in time may not accurately reflect the long-term value of the Company.

### ***Active Market***

There can be no assurance that an active market for the common shares will develop or be sustained. If an active public market for the common shares does not develop, the liquidity of a shareholder's investment may be limited and the share price may decline.

### ***Dividends***

To date, we have not paid any dividends and do not expect to do so in the foreseeable future. We currently intend to retain all future earnings for the operation and expansion of our business.

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

During the current reporting period, the Company earned service revenues and revenues from the sale of its diagnostic kits and 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.

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

The accompanying financial statements have been prepared by management in accordance with International Financial Reporting Standards. For quarterly reporting periods, the Company's financial statements are approved by the Audit Committee and the Board of Directors. For annual reporting periods, the Company's financial statements are approved by the Board of Directors upon recommendation by the Audit Committee. The integrity and objectivity of these financial statements are the responsibility of management. In addition, management is responsible for all other information in this report and for ensuring that this information is consistent, where appropriate, with the information contained in the financial statements.

In support of this responsibility, management maintains a system of internal controls to provide reasonable assurance as to the reliability of financial information and the safeguarding of assets.

In particular, the CEO and CFO or his designate are responsible for establishing and maintaining disclosure controls and procedures ("DC&Ps") and internal controls over financial reporting ("ICFRs") for the Company, and have:

- (a) designed such DC&Ps, or caused them to be designed under supervision, to provide reasonable assurance that material information is made known during the period in which the annual and quarterly filings are being prepared;

- (b) designed such ICFRs, or caused them to be designed under supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with IFRS;
- (c) evaluated the design and effectiveness of the Company's DC&Ps as of September 30, 2019;
- (d) determined that a material design weakness in the ICFRs may exist in terms of the inadequate segregation of certain duties, which is typical of development stage companies; mitigating factors, including dual-payment authorization policies and transparent internal financial transaction reporting processes, serve to minimize the risk that such design weakness could result in a material misstatement of results for the year-ended September 30, 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.

## **Glossary of Terms:**

**Biomarker:** Biological molecules, the presence or absence of which can be used to detect or monitor a state of disease or can be used to test the efficacy or safety of a drug in development

**FDA:** U.S. Food and Drug Administration

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

**R&D:** Research and development

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

**sqidworks:** Our diagnostic platform is a high-throughput fully automated microarray processing and analytical instrument

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