

# SQI DIAGNOSTICS INC.

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

**December 31, 2020** 

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

This Management's Discussion and Analysis ("MD&A") covers the interim financial statements for the three months ended December 31, 2020 and 2019. The unaudited financial statements and MD&A for the three months ended December 31, 2020 can be found on SEDAR at www.sedar.com.

All amounts are expressed in Canadian dollars unless otherwise indicated.

This discussion and analysis were prepared by management using information available as of March  $1^{st}$ , 2021.

This document contains forward-looking statements that relate to future events or future performance and reflect our expectations and assumptions regarding our growth, results of operations, performance and business prospects and opportunities. Such forward-looking statements reflect our current beliefs and are based on information currently available to us. In some cases, forward-looking statements can be identified by terminology such as "our goal", "may", "would", "could", "will", "should", "expect", "plan", "intend", "anticipate", "believe", "estimate", "predict", "potential", "continue", "positioned" or the negative of these terms or other similar expressions concerning matters that are not historical facts. The forward-looking statements in this document include, among others, statements regarding our future operating results, economic performance, product development efforts, and statements in respect of:

- *our requirement for, and our ability to obtain, future funding;*
- *our expected future losses and accumulated deficit levels;*
- technological advances of competitive products and general market competition;
- *our expectations regarding the acceptance of our products by the market;*
- our expectations regarding the progress and the successful and timely completion of the various stages of the regulatory clearance process;
- our strategy to develop new products and to enhance the capabilities of existing products;
- *our strategy with respect to research and development;*
- our dependence on expanding our customer base;
- our ability to obtain a sufficient supply of the components needed for our products;
- our ability to respond to legislative changes in the healthcare environment;
- *our plans to retain and recruit personnel;*
- our ability to develop and manufacture product to meet customer demands
- our plans to correct defects or errors in our systems; and
- *our strategy with respect to the protection of our intellectual property.*

A number of factors could cause actual events, performance or results, including those in respect of the foregoing items, to differ materially from the events, performance and results discussed in the forward-looking statements. Factors that could cause actual events,

performance or results to differ materially from those set forth in the forward-looking statements include, but are not limited to:

- uncertain future capital needs and additional financing;
- history of losses;
- market competition;
- market acceptance of products;
- complex regulatory compliance requirements;
- rapidly changing technology and customer requirements;
- research and development activities;
- *marketing and distribution*;
- reliance on key suppliers;
- legislative or regulatory change;
- key personnel;
- development or manufacturing delays;
- unknown defects or errors;
- foreign exchange fluctuations;
- intellectual property protection; and
- volatility of share price and an active market for our shares.
- other risks detailed from time-to-time in our ongoing quarterly filings, annual information forms, annual reports and annual filings with applicable securities regulators, and those which are discussed under the heading "Risk Factors".

Although the forward-looking statements contained in this management discussion and analysis are based on what we consider to be reasonable assumptions based on information currently available to us, there can be no assurance that actual events, performance or results will be consistent with these forward-looking statements, and our assumptions may prove to be incorrect. These forward-looking statements are made as of the date of this document.

#### **COMPANY OVERVIEW**

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

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

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

Under organ transplant, SQI is pioneering the development of an advanced diagnostic test that increases the chance of successful lung transplant by assessing the health of the donor organ prior to transplant surgery. The Company's developmental TORdx<sup>TM</sup> Lung Test can detect inflammation at the molecular level to assess the health of the donor lung, enabling surgeons to transplant healthy lungs which otherwise would have been rejected; there is currently no other such test. SQI is currently working with U.S. and Canadian regulators to seek the necessary approvals to market the TORdx<sup>TM</sup> Lung Test. Upon receipt of regulatory approval of the TORdx<sup>TM</sup> Lung Test, clinical development is planned for diagnostic tests designed to increase the chance of successful kidney and liver transplant.

SQI's clinical research partner at University Health Network (UHN), is increasing the procurement, stabilization and transportation of healthy donor lungs available for transplant by supporting perfusion centers across North America. Implementation of Ex-Vivo Lung Perfusion procedures (FDA approved 2019) has enabled lung transplant centers to increase the availability of donor lungs for transplant by nearly two-fold at some centers. Upon receipt of FDA market approval for the  $TORdx^{TM}$  LUNG Test, SQI intends to leverage its product offering within the EVLP market and direct to transplant hospitals.

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

# **Business Strategy**

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

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

Our business strategy is to become a rapid diagnostics leader by maximizing our research and development, our product offering and our testing services platforms. Our initial revenue streams are focused on proprietary advanced diagnostics that target organ transplant, autoimmune disease and COVID-19 testing. Our strategy includes:

- Successful completion of our diagnostic products under clinical development
- Successful marketing and business-to-business sales of our diagnostic tests
- Expansion of our commercial manufacturing and testing operations in the U.S.
- Upgrading our Toronto manufacturing infrastructure in order to produce approximately 4 million tests annually.
- Acquisition of key talent in our business
- Potential in-licensing and out-licensing of technologies and products
- Additional development of new diagnostic products through our research and development
- Acquisition of synergistic assets complementary to our business

# **Business Highlights During the Quarter:**

# **Impact of COVID-19 on our results:**

During the quarter, the Company's sales were adversely impacted by COVID-19. It is anticipated that kit sales to the UHN will increase as the hospital transitions back to normal operations. While it is not possible to determine how long the existing conditions will last, we anticipate that research kit sales with respect to transplants will revert to their pre-COVID-19 level once transplant operations return to normal.

In this quarter, the Company participated in the Canada Employment Wage Subsidy ("CEWS") program where payments received under this program served to partially offset employee wages during the period. Additionally, Management prioritized projects identified as key to delivering long term growth without impacting critical R&D and manufacturing programs. Central to this was the successful exercise of 19,074,997 warrants of the Company by certain insiders of the Company, who are also control persons, which delivered funding to the Company to support continued research into COVID-19 triage and testing products, as well as moving products forward through the regulatory approval process.

Despite the effects of COVID-19 as highlighted above, in this quarter, the Company was able to develop new business opportunities in the Life Science Operations segment in order to leverage its intellectual property and R&D capabilities.

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

During the quarter, the Company made progress in advancing its clinical development for the RALI-Dx<sup>TM</sup> product. The Company currently intends to file its RALI-dx<sup>TM</sup> submission to the FDA for EUA for use in the United States as well as for an Interim Order in Canada once its clinical development is completed.

#### **Financings:**

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

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

Additionally, during the quarter, several non-insiders exercised warrants at exercise prices ranging from \$0.20 to \$0.21 for total gross proceeds of \$457,000.

Subsequent to December 31, 2020, the Controlling Shareholders informed the Company of their intention to sell, from time to time, up to an aggregate of 15 million common shares at or around the prevailing market price of such shares at the time of such sales, and to use the proceeds of such sales (net of commissions, taxes and other selling costs) to finance the exercise of additional warrants held by such Major Shareholders at exercise prices ranging from \$0.12 to \$0.21 (the "Warrant Exercise") in order to fund the Company. On February 9, 2021, each of the Controlling Shareholders filed a Form 45-102F1 – *Notice of Intention to Distribute Securities under Section 2.8 of NI 45-102 Resale of Securities* (the "Sales Notices") disclosing their intention to complete the contemplated sales of shares to fund the Warrant Exercise. There is no assurance as to the timing of the transactions contemplated in the Sales Notices nor whether any such transactions will occur.

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

As part of its larger commercial strategy, the Company continued to develop its subsidiary in the United States: SQI US, Inc., the Company, has engaged with several contractors in marketing, business development, and clinical & regulatory. The goal is to have a physical base of operations by the end of the calendar year 2021.

# Financial Highlights for the Quarter

#### Three months:

Total revenues for the three months ended December 31, 2020 were \$161,000 compared to \$207,000 for the equivalent period last year. Product revenue, which includes revenue from kit sales was \$104,000 for the current quarter compared to \$147,000 for the same quarter last year. The decrease in product revenue is attributable to a combination of reduced diagnostic kit sales to a major customer as well as the absence of any platform sales in the current period.

Revenue from services in the first quarter were \$57,000 compared to \$60,000 in the same period last year. This reduction is primarily due to a pause in work done in conjunction with UHN on lung transplants, partially offset by revenue from a Life Science customer.

#### **Outlook**

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

We plan to accelerate the clinical development of our  $TORdx^{TM}$  LUNG Test. While COVID-19 has affected our reported revenues for the current periods, we believe this trend

is likely to reverse as we address the needs of the COVID-19 market, seek to gain regulatory approvals and increase sales of our Direct to Consumer ("DTC") products.

# SELECTED FINANCIAL INFORMATION

# **Quarterly Metrics and Analysis**

The table below summarizes quarterly financial information for the three months ended December 31, 2020.

	Three months ended December 31, 2020 (000s)	Three months ended December 31, 2019 (000s)
Revenue	\$161	\$207
Net Loss	(\$3,718)	(\$2,014)
Net Loss Per Share	(\$0.01)	(\$0.01)
Weighted Average Shares	309,530	232,113

#### Revenues

#### Three months:

During the three-month period ended December 31, 2020, the Company recorded revenue from the sale of custom kits, as well as service revenue to our biopharma and diagnostic customers. The table below summarizes revenue by category.

	Three months ended	Three months ended	
	<b>December 31, 2020</b>	<b>December 31, 2019</b>	
	(000s)	(000s)	
Product sales - Kits	\$104	\$136	
Product sales - Platforms		\$11	
Service revenue	\$57	\$60	
Total revenue	\$161	\$207	

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

#### **Net Loss**

#### Three months:

For the quarter ended December 31, 2020, the Company recorded a net loss of \$3,718,000 (\$0.01 net loss per share) as compared to a net loss of \$2,014,000 (\$0.01 net loss per share) for the quarter ended December 31, 2019. The net loss is higher in the current period, compared with the same period last year, due to a dedication of resources towards the Company's clinical and regulatory initiatives. Additionally, this year's expenses included higher stock-based compensation as a result of the grant of certain options to the new CEO of the Company. Laboratory and Research costs increased as the company embarked on a significant increase in clinical research to advance its COVID-19 suite of products through the regulatory process. Sales and Marketing expenses were lower in the current quarter compared to the same quarter last year due to lower contractor related costs as well as lower travel and marketing costs as a result of the travel restrictions imposed by COVID-19.

# **Operating Expenses**

#### Three months:

Research and development expenses include salaries and benefits from R&D staff, consulting fees, supplies and general laboratory operating expenses. R&D expenses, excluding amortization and stock-based compensation, for the three months ended December 31, 2020 were \$1,575,000 compared to \$1,006,000 for the same period last year. R&D costs increased due to clinical development and regulatory work related to our pursuit of EUA from the FDA.

Corporate and general expenses, excluding stock-based compensation, totaled \$815,000 for the three months ended December 31, 2020 as compared to \$364,000 for the three months ended December 31, 2019 resulting from increased professional fees. Professional fees were higher in the current quarter compared to the same period prior year due to higher legal and regulatory fees.

Sales and marketing expenses, excluding stock-based compensation, decreased to \$191,000 for the three months ended December 31, 2020 compared to \$259,000 for the three months ended December 31, 2019 due to lower contractor, headcount and travel and marketing costs primarily due to the COVID-19 pandemic.

Stock-based compensation expenses increased to \$954,000 for the three months ended December 31, 2020 compared to \$127,000 for the three months ended December 31, 2019. This increase was due to stock options granted to the new CEO as part of his compensation package.

# **Liquidity and Balance Sheet**

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

The Company believes it has sufficient capital to operate and execute its business plan through the next two calendar quarters. Factors that will affect our future anticipated cash requirements include, but are not limited to, the pace of expansion of our U.S. operations, the progress of our clinical development and research activities and regulatory decisions by the FDA and Health Canada.

Operating activities for the quarter ended December 31, 2020, were financed by cash on hand.

As of December 31, 2020, current assets were \$5,797,000 including \$5,086,000 of cash compared to \$2,493,000 including \$1,461,000 of cash at December 31, 2019. At December 31, 2020, the Company had a \$3,532,000 working capital surplus compared to a deficit of \$2,101,000 as of December 31, 2019. The higher surplus is due to a combination of increased liquid assets, as well as a change in classification of the debentures which matured and were subsequently extended; this extension changed the classification from a current liability to a long-term liability for the year.

Cash used in investing activities for the three months ended December 31, 2020 was \$42,000 as compared to \$29,000 for the three months ended December 31, 2019. Cash used in investing activities was primarily for information technology upgrades, leasehold improvements, lab equipment, and patents and trademarks.

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

# **Outstanding Capital Stock**

As of the date of this MD&A, there were 340,661,692 common shares issued and outstanding.

The following tables describe the securities that have been issued that are convertible under certain conditions into common shares: The Company had the following warrants outstanding as at the date of this MD&A:

Number of		
Warrants (000's)	<b>Exercise Price</b>	Maturity
1,388	\$0.21	March 10, 2022
45,739	\$0.20	December 20, 2022 – August 24, 2023
2,075	\$0.11	March 1 and 8, 2024
12,394	\$0.17	July 12, 2024
32,300	\$0.13	September 25 and October 22, 2024
622	\$0.085	February 20, 2025
44,444	\$0.12	February 14, 2025 and March 5, 2025
138,962		

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

<b>Number of Options</b>	Range of	Weighted average
(000's)	<b>Exercise Prices</b>	time to maturity
1,372	\$ 0.07 - 0.14	3.99 years
37,356	\$0.15 - 0.22	8.04 years
1,858	\$0.23 - 0.30	8.44 years
40,586		

# **Off-Balance Sheet Arrangements**

The Company has no off-balance sheet arrangements.

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

#### CRITICAL ACCOUNTING POLICIES AND SIGNIFICANT ESTIMATES

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

The significant accounting policies that management believes are the most critical in fully understanding and evaluating the reported financial results are included in the interim financial statements for the quarter ended December 31, 2020. Refer to the interim financial statements for the quarter ended December 31, 2020 for discussion on accounting policies and estimates that are most important in assessing, understanding and evaluating the Company's interim consolidated financial statements. Changes in these estimates and assumptions could have a material impact on the Company's interim consolidated financial statements.

#### **Risk Factors**

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 December 31, 2020, investors should give careful consideration to the following risk factors. Any of the matters highlighted in these risk factors could have a material adverse effect on our business, results of operations and financial condition, causing an investor to lose all, or part of their investment.

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

#### Risks Related to Pandemics, Epidemics or outbreak of infectious diseases

The economic effects of a pandemic, epidemic or outbreak of an infectious disease could adversely affect our operations or the market price of our common shares.

Public health crises such as pandemics, epidemics or similar outbreaks could adversely impact our operations or the market price of our common shares. In December 2019, a novel strain of coronavirus ("COVID-19") was reported to have surfaced in Wuhan, China and has reached multiple other countries, resulting in government-imposed quarantines, travel restrictions, school closures and other significant restrictions on business operations imposed by governmental authorities in North America, Europe and worldwide. On

January 30, 2020, the World Health Organization declared the outbreak of the COVID-19 a "Public Health Emergency of International Concern." On January 31, 2020, U.S. Health and Human Services Secretary Alex M. Azar II declared a public health emergency for the U.S. to aid the U.S. healthcare community in responding to COVID-19, and on March 11, 2020, the World Health Organization characterized the outbreak as a "pandemic". The extent to which the COVID-19 impacts our operations or market price of our common shares will depend on future developments, which are highly uncertain and cannot be predicted with confidence, either internationally or within the U.S. or Canada, including the duration of the outbreak, new information that may emerge concerning the severity of the COVID-19 and the actions to contain the virus or treat its impact, among others. COVID-19, however, has already resulted in significant volatility in the world and the national trading markets.

The spread of COVID-19 may impact our operations, including a sustained delay in returning to the number of lung transplants performed pre-COVID-19. Our existing and potential customers such as Biopharma companies may redirect resources away from current research and or product development priorities to COVID-19. The spread of an infectious disease, including COVID-19, may also result in the inability of our suppliers to deliver components or raw materials on a timely basis or at all. The significant spread of COVID-19 within the U.S. and Canada resulted in a widespread health crisis and has had adverse effect on the national economies generally, the markets that we serve, our operations and the market price of our common shares.

# Impact of COVID-19 on Our Results:

During the quarter, the Company's sales were adversely impacted by COVID-19 due to restrictions currently in place at certain customer sites. It is anticipated that revenues may continue to be adversely impacted for the remainder of the calendar 2021 until these restrictions are lifted and operations return to normal. In particular, the Company's kit sales to one of its major customers have declined.

During the quarter ended December 31, 2020, the Company participated in the Canada Employment Wage Subsidy program, where payments of \$81,000 received under this program served to partially offset employee wages during the period.

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

#### Intellectual Property Protection

Our commercial success depends, in part, upon our ability to protect our intellectual property and proprietary technologies. We rely on patent protection, where appropriate and available, as well as a combination of copyright, trade secret and trademark laws, and nondisclosure, confidentiality and other contractual restrictions to protect our proprietary technology. However, these legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. Our

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

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

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

#### Volatility of Share Price

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

#### Active Market

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

#### Dividends

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

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

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

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

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

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

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

The accompanying interim financial statements have been prepared by management in accordance with International Financial Reporting Standards. For quarterly reporting periods, the Company's interim financial statements are approved by the Audit Committee and the Board of Directors. For annual reporting periods, the Company's financial statements are approved by the Board of Directors upon recommendation by the Audit Committee. The integrity and objectivity of all financial statements are the responsibility of management. 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 interim 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, 2020;
- (d) have concluded that a material design weakness in the ICFRs may exist in terms of the inadequate segregation of certain duties, which is typical of development stage companies; mitigating factors, including dual-payment authorization policies and transparent internal financial transaction reporting processes, serve to minimize the risk that such design weakness could result in a material misstatement of results for the three-month period ended December 31, 2020; and
- (e) have concluded that, other than the item described above in sub-point (d), there are no additional material design weaknesses in the DC&Ps or ICFRs, and that the effectiveness of the DC&Ps is sufficient to expect the prevention or detection of material misstatements of results.

The interim financial statements include amounts that are based on the best estimates and judgments of management. The Board of Directors is responsible for ensuring that management fulfills its responsibility for financial reporting and internal control. The Board of Directors exercises this responsibility principally through the Audit Committee. The Audit Committee consists of three directors, all of whom are not involved in the daily operations of the Company and one of whom is independent. The Audit Committee meets with management and the external auditors to satisfy itself that management's responsibilities are properly discharged and to review the interim financial statements prior to their presentation to the Board of Directors for approval.

# **Glossary of Terms:**

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

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

**R&D:** Research and development

sqidlite<sup>™</sup>: Our bench-top diagnostic system – fully automated bench top microarray processing system

**sqid-X**<sup>TM</sup>: sqid-X<sup>TM</sup>: sqid-X<sup>TM</sup>: