



## **SQI DIAGNOSTICS INC.**

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

**September 30, 2014**

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*This Management's Discussion and Analysis ("MD&A") covers the audited financial statements for the years ended September 30, 2014 and 2013. The annual audited financial statements and MD&A for the year ended September 30, 2014 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 16, 2014.*

*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 plans to market, sell and distribute our products in Canada and the United States;*
- our plans in respect of strategic partnerships for research and development;*
- our ability to obtain a sufficient supply of the components needed for our products;*
- our plans to retain and recruit personnel;*
- 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:*

- the extent of our future losses;*
- our ability to obtain the capital required to fund development and operations;*
- development or commercialization of similar products by our competitors;*
- our ability to develop and market our products;*
- our ability to comply with applicable governmental and securities regulations and standards;*
- our ability to develop and commercialize our technologies;*

- *delays or failures in our ability to develop and implement new diagnostic products;*
- *our ability to expand our customer base;*
- *our ability to market, sell and successfully commercialize our products;*
- *our ability to attract and retain skilled and experienced personnel;*
- *the impact of changes in the business strategies and development priorities of our strategic partners;*
- *loss of suppliers or increases to the cost of the components of our systems;*
- *the impact of legislative changes to the healthcare system and regulatory process;*
- *our ability to maintain effective internal control over financial reporting;*
- *damage to our manufacturing facility or its failure to accommodate future sales growth;*
- *the impact of unknown defects or errors and product liability claims;*
- *foreign currency fluctuations;*
- *our ability to obtain patent protection and protect our intellectual property rights and not infringe on the intellectual property rights of others;*
- *the expense and potential harm to our business of intellectual property litigation;*
- *stock market volatility;*
- *the fact that further equity financing may substantially dilute the interests of our shareholders; and*
- *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.*

## **OVERVIEW**

SQL Diagnostics Inc. (“SQL Diagnostics” or “SQL” or the “Company”) was founded in 1999 on the straightforward idea that the number of blood tests performed to diagnose a patient’s disease state was large and growing and that reducing the effort to complete these multiple tests would create a significant benefit. Since then, SQL has invested significant resources to develop products and automated systems that enable our customers to obtain multiple results from one single test well (multiplexing), saving them time and money.

SQL Diagnostics Inc. is now a leading innovator in the multiplexed microarray diagnostics and life sciences tools arena. Our multiplex tests and automated platforms together form a powerful tool for the design, development and running of tests in three key markets:

(1) Drug Development Testing - blood testing in clinical trials for pharmaceutical and biotechnology companies developing novel drugs with low regulatory requirements;

(2) Human Diagnostic Testing - diagnostic tests for humans developed for our strategic customers including DNA-based tests for infectious disease and in-house developed tests for regulatory cleared *in vitro* diagnostic (IVD) immunology testing done in reference laboratories for the diagnosis and monitoring of autoimmune diseases. There is a large market for unregulated applications although IVD tests have relatively rigid regulatory requirements; and,

(3) Animal Health Diagnostic Testing – typically unregulated diagnostics tests used for animal health including tests for infectious diseases, food safety and routine companion animal tests.

## **2014 – A FOUNDATIONAL YEAR**

2014 was a year of building a solid foundation in the Drug Development Tools and Services business. In 2014 we signed 6 master service agreements, 4 of these with customers which are among the top ten pharmaceutical companies in the world.

We achieved our key priorities in 2014:

- We broke into a market dominated by large competitors.
- We validated our products as superior to existing tests in many respects.
- We sold our customers on the value proposition that SQI's technology is a PLATFORM that improves their business across multiple product lines.
- We challenged our competitors by delivering customer delight with our custom product service delivery and tests.
- We won repeat business.
- We opened up new markets for our products leveraging our expertise, collaborations with large pharmaceutical companies and our understanding of industry needs.
- We demonstrated our flexibility by developing and delivering a wide array of new product types and in turn diversified our revenue sources.
- We re-established our regulated product capability by winning FDA clearance for our newest multiplexed celiac diagnostic test.
- And, most importantly, we positioned SQI to place a significant number of diagnostic platforms at our customers in 2015. These placements are the drivers for delivering on-going revenues from our customers in the years to come.

## **OUTLOOK - OUR STRATEGY for 2015**

To achieve our vision and drive our future growth, we have 5 strategic objectives.

### **1. ACHIEVE SUSTAINABLE REVENUE VELOCITY**

Our main objective for 2015 is to leverage the success achieved in 2014 and to sell and place sqidlite™ analyzers into our customers' labs, have them further validate the tests we have delivered to them and drive revenue growth across the installed customer base selling custom and routine test kits. Simply put – we aim to achieve sustainable revenue velocity. Our goal is that **each** sqidlite platform when being fully utilized by our customers generates over \$2 million in recurring revenue.

Our sales strategy is to:

- Win new customers by leveraging our market-leading custom product superiority as an entry point;
- Grow our installed base by converting development customers to steady customers that have an installed SQI platform or platforms in their laboratories;

- Sell customers a growing number of custom test kits (consumables) to run on these platforms;
- Continue to grow the business opportunities within existing customers and identify new revenue opportunities with those customers, building on the value our technologies and platforms provide them. Our large pharmaceutical customers' stated objective in placing our platforms in their labs is to utilize the technology across multiple products and beyond the initial custom tests that we were first engaged to develop;
- Win ancillary, high volume product business alongside our high margin, entry-point custom products. We expect that we can leverage our success with customers to sell them other products that we have available to replace current "low-tech", "single-test" products with our automated, multiplex products;
- Keep the top of our sales funnel refreshed with new customer opportunities across all lines of our business. To achieve this we also intend to add to our sales team in 2015 and to continue our strategy of direct sales, collaborative conference presentations with our customers and contributions to pharma and biotech industry working groups.
- Looking forward, we expect that we could have over 10 drug development customers with 1 or more systems in place by the end of 2015. Each of these systems is capable of processing enough product to generate well in excess of \$2 million in revenue for SQI when operating at capacity.

## **2. DELIVER DIFFERENTIATED CUSTOMER EXPERIENCES**

Our value proposition is consistent across our markets. We provide state of the art test kits and platforms that reduce the amount of work performed while delivering superior product performance. We do this through "multiplexing" and automation. Multiplexing allows our customers to get many results from a single test. To date, we have built custom tests in our drug development market that have as many as 21 unique results from a single SQI test. In other words, we take away the effort our customers would have previously needed to develop 21 different tests – now 1 test provides 21 results; reduce the effort to validate 21 different tests; reduce the effort to collect very valuable blood samples to allow the customers to run 21 different tests from 21 times less blood; and, finally, our automated systems will run the SQI tests and complete the analysis and reporting of the results. Our scientists are developing these highly technical products in timelines and at levels of performance that we believe to be unparalleled in the industry.

It is fair to say that in many cases our customers in the drug development markets are using our products in a way that allows them to generate many more results than they would have in the past and we believe that in many cases we are creating new markets with our technologies.

Our strategic objective is to continue to collaborate with the drug development industry and to continue to push the envelope with them to deliver leading edge, custom products that address the current needs of reducing effort and cost and to create new markets based on the capabilities of our products.

### **3. EXPAND OUR PRODUCT REACH**

Combined, our current pharma and biotech customers have a total of approximately 130 drugs in development and are estimated to be adding 10 new products into their drug development pipeline each year. Our goal is to expand our customers' use of our tests beyond the initial prototype products we are working on, and, we expect to have customers with multiple projects delivering multiple revenue sources concurrently. Our entry point into our customers is custom-developed tests. Our goal is to expand beyond these high value tests and to also sell other, high volume routine tests that can be run on their qidlite platforms.

### **4. MAINTAIN INDUSTRY-LEADING TECHNOLOGIES IN HIGH VOLUME PRODUCT MARKETS**

Whether we are developing tests to assist drug developers in their clinical programs or automating DNA tests for customers in the infectious disease markets, our products are laser focussed on high throughput solutions in markets that have been largely underserved by multiplexing and automation. Over the last 18 months we have evolved the business to diversify our revenue risk.

SQI has moved from a focus just on developing FDA cleared products for autoimmune disease. We have expanded into custom products and services for drug developers, automated an infectious disease DNA test in animal health (milk testing for infections in dairy cows) and are looking forward to applying our core technologies in testing in multiple areas of human and animal health. These DNA-based tests, the majority of which are completed using agar-based cultures, currently take several days to complete. The DNA-based tests we are commercializing when run on SQI platforms are finished in several hours. The reduction in time, combined with a more precise diagnostic result for infection, in either human or animal health markets is meaningful and offers significant benefits to patient outcomes and lowers cost to the health-care system. These tests use multiplex DNA technology to more accurately identify the cause of dangerous blood infections like sepsis enabling faster, more targeted treatment. The tests we are developing with our customers offers this advantage at a total cost of delivery that we believe will be highly competitive in the market. In fact test we are developing for one of our customers are currently processed in human diagnostic central labs at very high volumes with some targeted customers running up to 1 million tests annually.

Tests in the animal health market use the same technology as the human DNA tests, and have the potential to significantly reduce the time to a diagnostic result in dairy cows with mastitis. The key benefit in this market is more immediate segregation and targeted treatment significantly reducing costs associated with herd infections. It has been estimated that there are approximately 60 million such tests performed annually in North America. Sepsis, a serious infectious disease affecting humans that can be detected using the same technology, affects approximately 1,000,000 people in North America annually and is estimated to cost the healthcare system over US\$1 billion each year – earlier diagnosis and treatment could significantly improve outcomes and reduce costs.

### **5. FOCUS ON NEAR-TERM PHARMA AND DIAGNOSTIC REVENUE OPPORTUNITIES**

SQI started as a multiplexing company focused on autoimmune disease testing in humans. Today, we are focussed on expanding the application of our technology to address needs in the drug development and other diagnostic markets while maintaining our progress in autoimmune disease. This change of focus is being successfully executed in order to win revenue in markets requiring less investment, much less regulatory effort and where there is a much larger aggregate opportunity. We are in the process of unlocking the opportunities in a wide range of projects and

across multiple product lines. We believe that this strategy will achieve our goal of sustainable revenue velocity sooner.

As such, the Company commercializes its technology through two principal and integrated lines of business in the three main markets discussed above:

### **Drug Development Tools and Services (DDTS)**

Drug Development Tools and Services is focused primarily on pharmaceutical companies, biotechnology companies, and vaccine companies along with the Contract Research Organizations (CROs) that serve them. These companies are required to understand many biological responses to their in-development drugs and these responses are expressed through the production of a wide range of proteins and antibodies in animals and humans during a drug's development. Detecting, measuring and understanding these responses can impact the design, evaluation and selection of drug candidates and the course of development of a drug. Common types of testing to measure responses are categorized as follows: immunogenicity; anti-drug antibody ("ADA"); inflammatory; biomarker and epitope mapping. The use of these common tests has grown dramatically over the last decade, enabled by testing innovation and the rise of data management and informatics. And, more recently, FDA guidance to drug developers issued this year is expected to influence this market positively as it provides more direct guidance to industry related to using these tests in their drug development programs. Over the last 18 months, SQI used the widely available *draft* guidance from the FDA to build products that specifically addressed the expected needs of the industry to follow the now issued guidance.

The quantification of these biologic markers (antigens, antibodies, cytokines, and other proteins) is traditionally very laborious. Not only is the testing itself manually intensive, because each drug or vaccine candidate is unique and proprietary, but also because each custom *immunogenicity* test must be designed, developed and validated before it can be performed. Each of these development processes is done one at a time and is traditionally very labour intensive as well.

Custom multiplexed tests and automated diagnostic platforms from SQI have the potential to change the way pharmaceutical companies design and conduct their testing of these biologically important markers. Shortening the time and expense to conduct such testing could enable pharmaceutical companies to advance their pipeline of new drug candidates more quickly, extending the time period under patent protection, and reducing their overall costs; critical issues for these companies.

The Company has also expanded its customer base in the DDTS business segment to include diagnostic companies that have large menus of content that would benefit from conversion to SQI's automated multiplexing platforms. These targets include but are not limited to human IVD diagnostic companies in similar or complementary markets of immunology and autoimmune disease and, more recently, animal health diagnostic companies that focus on the agricultural and companion animal markets.

SQI's business model for DDTS customers is to sell comprehensive "turnkey" services including the initial rapid design, development and validation of custom multiplex tests kits. The customer then contracts SQI to manufacture these custom kits for purchase and use in their pre-clinical and clinical drug trials, with testing conducted at the customer or its CRO. In some cases, SQI can also provide sample analysis performed at the Company, as a service.

In fiscal 2014, the Company expanded the application of its technology into the molecular diagnostics arena. Through a partner-lead project, SQI has automated a DNA-based 19 pathogen, 31 probe detection panel, for application in human and animal health diagnosis. Management believes that the rapid turn around and success of this first DNA project has important positive implications and further, that automation of these tests incorporating high volume testing capacity will position SQI and our customer to stake out a position of leadership in this fast growing market.

As we commercialize our products in the pharma market, customers are choosing multiplex tests from SQI because they combine multiple tests that they use in a particular application into a single test providing all of their required results, while maintaining or exceeding the technical performance to which they are currently accustomed. Further, we fully automate the processing of these tests on our systems so that with as little as 15 minutes of operator hands on time they can run many samples, achieving high throughput, in a run and walk away mode. Our technology meets or exceeds all US Food and Drug Administration (“FDA”) and European Medicines Agency (“EMA”) immunogenicity and biosimilar test guidelines.

### **In Vitro Diagnostics (IVD)**

SQI is also advancing a pipeline of **multiplexed IVD products** targeting protein and antibody biomarkers relevant to autoimmune and other immunological diseases. These tests are developed, validated and manufactured by the Company for direct marketing and sales to reference labs once cleared by regulators such as the FDA.

Our target customers require diagnostic processing equipment and consumable tests (together “systems”) that are capable of processing large numbers of patient samples to detect and quantify multiple and varied types of human antibodies, isotypes (different forms of the same antibody) and sub-classes of antibodies. Our systems and multiplexing technologies enable many tests to be completed in a single well of one of our consumable test kits at low cost and with minimal labour requirements using our semi-automated or fully-automated high-throughput systems. Our systems have the potential to increase a laboratory’s throughput with significantly less labour, consumables and other costs.

### **Platforms**

SQI has developed a range of analytical platforms that meet the varying needs of our customers in both our DDTS and IVD markets:

- Our sqid-X™ System is a semi-automated bench-top platform that incorporates all of SQI’s technology with the exception of automated fluidics handling and is targeted at early adopters; earlier stage, lower volume customers; and, customers who intend to complete custom test development work at their sites.
- Our mid-range sqidlite™ Bench-Top Diagnostic System (sqidlite), offers laboratories of all sizes flexible, configurable, fully automated workflow solutions for processing protein and antibody multiplexed immunoassays in both our DTS and IVD markets. Sqidlite integrates all test fluidics, test kit processing and analyzing functions in a user-friendly bench-top footprint.
- Our high-throughput sqidworks™ Diagnostic Platform (sqidworks) is a fully-automated microarray processing and analytical instrument, primarily suited for high-volume reference laboratories

## **COMMERCIALIZATION AND DEVELOPMENT ACTIVITIES FISCAL 2014**

Throughout fiscal 2014, the Company continued to focus its business development activities on expanding its customer base, progressing current customers who are commissioning and evaluating prototype tests to ultimately purchasing production scale volumes of test kits, and expanding the number of products being purchased or evaluated by each customer. The Company currently has revenue generating projects underway with four of its six previously announced customers. These projects have produced \$119,000 in revenue for the year ended

September 30, 2014. Management continues to engage with the other announced customers to explore opportunities to sell products and services.

New customer generation efforts continue to be largely focused on pharmaceutical, biotech and vaccine companies that currently use single-plex immunogenicity tests in their product development activities, as well as the CROs that service the immunogenicity testing needs of pharmaceutical companies on an outsourced basis. For the quarter and year ended September 30, 2014, we continued to report revenue from the Drug Development Tools and Services side of our business.

Although we have made significant technical progress on all of the projects on which we have been engaged we are disappointed with the speed at which these projects have progressed. Despite our having achieved project deliverables that met or exceeded specifications and doing so within agreed timelines, decisions regarding the advancement of the projects rest with our customers and we are not able to control the timing of such decisions.

A summary of the commercialization and development activities undertaken by SQI over fiscal 2014 is described below. The names of certain customers or potential customers have been omitted owing to confidentiality agreements with these entities; instead they are referred to as "Global Pharma 1", "Global Pharma 2", "Global Pharma 3", "Global Pharma 4", respectively.

#### New Customer – UK-based DNA diagnostic company

- On August 22, 2014 the Company announced it had entered into a Master Services Agreement with a UK-based company to automate their DNA-based pathogen detection test on our **sqidlite** platform. SQI delivered an automated working prototype to the customer in a demonstration at our premises. The test uses 31 DNA probes to detect and identify 19 pathogens in a single well. The test that was demonstrated is used to identify pathogens in raw milk from dairy cows, specifically targeting detection and identification of pathogens causing mastitis. Currently, dairy cows are routinely tested for health through a global network of laboratories and when symptoms of bacterial infection appear, pathogens are commonly detected using traditional plate cultures. The new application can be used for much faster and more accurate identification of multiple pathogens simultaneously. The UK-based company is developing additional tests for agriculture, food safety and human pathogen testing such as blood screening, intended to screen high volumes of samples on a regular basis. The use of SQI's technology platforms in molecular diagnostic testing is a novel application providing new revenue opportunities for the Company.
- In September of 2014, a work plan and quote was submitted to the customer for the second stage of this project. This includes the scale-up of the manufacturing processes and quality procedures (technology transfer), the completion of the automation of the **sqidlite** system for the detection of pathogen-derived DNA, and to lead or manage the automation of the process steps required to extract and amplify DNA from samples. Discussions and work plan preparations are ongoing. It is expected that the first product focus will be a panel to detect pathogens in human blood and in parallel it is expected that SQI and this customer will continue work related to product application in the animal health dairy market. Subsequent to year end a contract was signed for the technology transfer process and it is expected that SQI will announce further commercial progress in early 2015.

#### Global Pharma 4:

- On May 5, 2014 the Company entered into an agreement with its fifth customer, one of the ten largest pharmaceutical companies in the world, referred to by SQI as Global Pharma 4. This customer is paying SQI to develop and validate two custom multiplex ADA tests, which are typically designed to measure and characterize the animal and

human immune response to a drug. Our customer will evaluate these two products using one of its already established drugs in order to assess the capabilities and performance of SQL's technologies. As such, this is an initial entry point into a much larger opportunity to provide ADA testing for one or more of the numerous early stage drug candidates in their development pipeline.

- In the fourth quarter of fiscal 2014, SQL provided the customer with initial data from the prototype development work, which reportedly exceeded the customer's expectations. The customer asked SQL to pause development on one of the ADA tests and attempt to achieve similar results with an additional project. The pause and launch of the new project was driven by the excellent drug tolerance results achieved in the initial ADA test; however, it resulted in a delay for us in advancing toward revenue on the initial aspect of this contract. Having said that, we believe that establishing our products as having superior drug tolerance compared to alternative methods and products is important as this performance criterion has been emphasized by the FDA in recently published guidance. Upon completion of the new project SQL was asked to submit a proposal for a third project. Subsequent to year end the Company received a contract for this third development project from this customer. The Company is negotiating commercial contracts with this customer building upon the completed development projects. These negotiations include the delivery of a sqidlite platform and validation test kits expected to produce revenue in fiscal second quarter of 2015.

#### Global Pharma 1:

- During the year ended September 30, 2013 the Company entered into an agreement with Global Pharma 1 for the development and evaluation of a proof-of-concept ADA test to detect and quantify the immune response in four animal species to a new class of drug.
- During the second quarter of fiscal 2014, the Company successfully expanded its product development relationship with Global Pharma 1 entering into an agreement to develop a 21-plex protein microarray for use in identifying specific immunogenic regions within one of its drug candidates (also known as "epitope mapping"). During the third quarter, SQL delivered our initial data resulting from the prototype of this test to the customer and this customer is in the process of completing planning for the adoption and use of this test. This process, should it proceed, would involve final testing of their patient samples at SQL and the installation of a sqidlite system at their facility. The system and test kits, at volumes commensurate with their clinical program, would be purchased subsequent to their validation of their custom epitope mapping test.

#### Global Pharma 2:

- During the year ended September 30, 2013 the Company entered into a master services agreement with Global Pharma 2, which governed the development and evaluation of a 21 biomarker ADA test to measure the immune responses in clinical trials to the customer's in-development biologic drug. Major development milestones have been achieved on this project and the Company believes that it exceeded performance expectations for the prototype. The Company continues to work with this customer to identify follow-on opportunities for the ADA product offering.

#### Isis Pharmaceuticals:

- During the first quarter of fiscal 2014, the Company entered into an agreement to develop an 8-plex multiplexed ADA test for Isis Pharma. The Company completed the prototype project and presented test data to Isis and believes that it has met or exceeded the customer's expectations. The Company continues to work on finalizing a commercial contract with Isis's CRO to implement the SQL-developed test in clinical testing. Management currently expects the CRO's validation work to start in the first quarter of calendar 2015.

Global Pharma 3:

- During the first quarter of fiscal 2014, the Company entered into a commercial product development and Master Services Agreement with Global Pharma 3, an Irvine California-based global pharmaceutical company. Under the terms of the first contract, SQI was paid to build a 6-plex ADA test to detect and measure immunogenic responses to a drug in the customer's extensive drug pipeline. The Company generated initial revenue through the test development phase of this contract, which involves the evaluation of the test using pre-clinical samples. All development milestones were met.
- Subsequent to year end the Company was negotiating a new contract with this customer to develop another custom ADA test for a new drug molecule. The Company expects that this test will be validated using customer samples at SQI which may lead to commercial adoption and implementation by this customer.

The Company's current focus is to deliver on the customer-targeted proof-of-concept tests to generate near-term revenues and establish a positive track-record in this market. SQI is delivering on this goal and has demonstrated to its first target customers that it can deliver the custom Ig\_plex tests specific to their drug targets within agreed upon timelines. The Company believes that this success will lead to revenue from these and other customers in its sales pipeline.

Although the majority of our time and resources were devoted to the near-term opportunities in the pharmaceutical and biotech development markets in fiscal 2014, the Company also continued to advance its pipeline of IVD tests, albeit at a slower pace. SQI's lead IVD test is its multiplexed Ig\_plex® Celiac DGP Panel, which provides clinicians with a valuable and rapid tool to quantify the levels of multiple key biomarkers associated with celiac disease. In February of 2014 the Company obtained a license from Health Canada permitting the Company to market this panel. SQI received clearance from the United States Food and Drug Administration (FDA) allowing Company to market its proprietary Celiac Panel in the United States shortly after year end. According to the New England Journal of Medicine<sup>1</sup>, it is estimated that 1 in 100 people in the United States is affected by celiac disease.

The Company is currently focusing on the development of Ig\_plex Vasculitis and Ig\_plex Lupus IVD products.

The development status of the Company's current IVD portfolio of products is summarized in the table below:

DEVELOPMENT STATUS – IVD						
PRODUCT	STAGE OF DEVELOPMENT					
	Candidate Panel	Proof-of-Concept	Assay Development	Automation	Validation	Approval/Clearance
Ig_plex Celiac DGP (Quantitative) (1)						
Ig_plex Vasculitis						
Ig_plex RA (Quantitative)						
Ig_plex Lupus						
Ig_plex IBD/Crohn's						

(1) Approved or cleared in the U.S. and Canada.

<sup>1</sup> . Celiac Disease, Alessio Fasano, M.D., and Carlo Catassi, M.D., M.P.H., N Engl J Med 2012; 367:2419-2426, December 20, 2012.

The tests developed by SQI have the potential to save large volume reference labs both time and money and may also improve the data collected in each test. Successful penetration of the IVD testing market is difficult to achieve based on a single test, particularly when that test requires investment by a lab in a hardware platform. By adding further qualitative tests to the SQI menu of regulatory cleared tests, management believes the business case for switching to the SQI platform becomes compelling. As a consequence, the Company plans to continue to invest to develop and achieve clearance for the tests listed above. In light of the Company's limited resources such investment will rank behind investing in our tools and services business opportunities as those projects can deliver revenue and cash flow more quickly

## **CORPORATE FINANCING TRANSACTIONS**

On January 27, 2014 the Company completed a non-brokered private placement of 2,965,000 units of the Company at \$0.50 per unit for gross proceeds of \$1,483,000.

Each unit consists of one common share and one common share purchase warrant. Each common share purchase warrant entitles the holder to purchase one common share at a price of \$0.65 for a period of two years from the date of issuance. The proceeds from the issuance of units are allocated between capital stock and warrant capital based on their relative fair values, with \$971,000 being allocated to warrant capital. The fair value of the warrants was estimated using the Black-Scholes pricing model with the following assumptions: share price \$0.52; dividend yield 0%; risk free interest 1.25%; volatility 133%; and an expected life of 2 years. Expected volatility is based on historical volatility.

In connection with the private placement, the Company paid a finder's fee of \$104,000 and issued 296,500 compensation warrants exercisable for a two year period from the closing of the private placement. Each compensation warrant is exercisable into one common share and one warrant at a price of \$0.50. Each underlying warrant included in the compensation warrant is exercisable into one common share at a price of \$0.65 for a two year period from the date of the private placement. The fair value of the compensation warrants was estimated at \$95,000 using the Black-Scholes pricing model with the following assumptions: share price \$0.52; dividend yield 0%; risk free interest 1.25%; volatility 133%; and an expected life of 2 years. Expected volatility is based on historical volatility. Broker warrants and related financings were not measured at the fair value of the services received as the fair value of such services was not reliably measurable. The total share issuance costs were \$210,000.

On April 10, 2014 the Company completed public offering of 8,400,000 units of the Company at a price of \$0.50 per unit for gross proceeds of \$4,200,000.

Each unit comprises one common share of the Company and one common share purchase warrant. Each warrant is exercisable at a price of \$0.65 and entitles the holder thereof to acquire one Common Share until April 10, 2016. The proceeds from the issuance of units are allocated between capital stock and warrant capital based on their relative fair values, with \$1,428,000 being allocated to warrant capital. The fair value of the warrants was estimated using the Black-Scholes pricing model with the following assumptions: share price \$0.50; dividend yield 0%; risk free interest 1.08%; volatility 131%; and an expected life of 2 years. Expected volatility is based on historical volatility.

The Company paid the Agent a fee equal \$294,000 and issued 588,000 compensation warrants exercisable until April 10, 2016. Each warrant is exercisable into one common share and one warrant at a price of \$0.50. Each underlying warrant is exercisable into one common share at a price of \$0.65 until April 10, 2016. The fair value of the compensation warrants was estimated at \$191,000 using the Black-Scholes pricing model with the following assumptions: share price \$0.50; dividend yield 0%; risk free interest 1.08%; volatility 131%; and an expected life of 2 years. Expected volatility is based on historical volatility. Broker warrants and related financings were not measured at the fair value of the services received as the fair value of such services was not reliably measurable. The total share issuance costs were \$701,000.

On December 4, 2012 the Company extended the expiry of 1,199,052 warrants exercisable at a price of \$4.00 per share to December 4, 2013. All other terms of the warrants remained unchanged. The fair value of the extension was estimated using the Black-Scholes pricing model with the following assumptions: share price \$0.34; dividend yield 0%; risk free interest 1.07%; volatility 103%; and an expected life of 1 year. Expected volatility is based on historical volatility. As a result of the extension \$4,000 was recorded in warrant capital with a corresponding reduction in contributed surplus. On December 4, 2013, the Company received approval to extend the expiry of these warrants for an additional 12 months to December 4, 2014. All other terms of the warrants remained unchanged. The fair value of the extension was estimated using the Black-Scholes pricing model with the following assumptions: share price \$0.70; dividend yield 0%; risk free interest 1.1%; volatility 154%; and an expected life of 1 year. Expected volatility is based on historical volatility. As a result of the extension \$170,000 was recorded in warrant capital with a corresponding reduction in contributed surplus.

On October 10, 2013, the Company extended the expiry of 2,276,000 warrants by 36 months to October 25, 2016. The warrants were issued in October 2011 in connection with a private placement. All other terms of the warrants remained unchanged. The fair value of the extension was estimated using the Black-Scholes pricing model with the following assumptions: share price \$0.76; dividend yield 0%; risk free interest 1.2%; volatility 96%; and an expected life of 3 years. Expected volatility is based on historical volatility. As a result of the extension \$616,000 was recorded in warrant capital with a corresponding reduction in contributed surplus. In addition, 86,040 warrants with an expiry of October 26, 2013 expired unexercised and \$54,000 was transferred to contributed surplus upon expiry.

On May 8, 2014, the Company received approval from the TSX Venture exchange to extend the expiry of 3,508,171 warrants with an exercise price of \$2.50 issued in connection with a private placement which was completed on June 20, 2014. The warrants which had expiry dates of May 10, 2014, May 16, 2014, June 13, 2014 and June 19, 2014 were extended to May 10, 2015, May 16, 2015, June 13, 2015 and June 19, 2015. All other provisions of the warrants remain unchanged. The fair value of the extension was estimated using the Black-Scholes pricing model with the following assumptions: share price \$0.37; dividend yield 0%; risk free interest 1.04%; volatility 120%; and an expected life of 1 year. Expected volatility is based on historical volatility. As a result of the extension \$147,000 was recorded in warrant capital with a corresponding reduction in contributed surplus. In addition, 210,491 warrants with an expiry dates of May 10, 2014, May 16, 2014, June 13, 2014 and June 19, 2014 expired unexercised and \$108,000 was transferred to contributed surplus upon expiry.

## SELECTED FINANCIAL INFORMATION

The table below summarizes annual financial information for the fiscal years ended September 30, 2014 and 2013.

	Year ended September 30, 2014 (000s)	Year ended September 30, 2013 (000s)
Revenue	\$ 119	\$ 3
Net Loss	\$ 5,460	\$ 6,207
Net Loss Per Share	\$ (0.11)	\$ (0.15)
Weighted Average Shares	50,982	41,961

Revenue for the year ended September 30, 2014 was \$119,000 versus \$3,000 for the year ended September 30, 2013. Revenue in the year ended September 30, 2014 was from the delivery of proof-of-concept tests for customers in our Diagnostics Tools and Services (DTS) business. The revenue is attributable to development projects with four customers, as discussed in more detail earlier in this discussion. Revenue grew each quarter in 2014 as the Company signed additional services agreements and achieved success in its development projects for these customers.

The net loss for the year ended September 30, 2014 was \$5,460,000 (\$0.11 net loss per share) as compared to \$6,207,000 (\$0.15 net loss per share) for the year ended September 30, 2013. The decrease in net loss for the year ended September 30, 2014 compared with the loss for the year ended September 30, 2013 is a result of reductions in Corporate and General and Research and Development expenses.

Research and development (R&D) costs, excluding amortization, stock based compensation and the SR&ED Investment Tax Credit (SR&ED ITC) were \$3,014,000 for the year ending September 30, 2014 compared to \$3,320,000 for the year ending September 30, 2013. The lower R&D costs in fiscal 2014 were a result of the Company completing its validation work on the Celiac DGP test in the first quarter of fiscal 2014 with regulatory submissions following in the second quarter of fiscal 2014. R&D costs in fiscal 2013 included significant expenditures on verification and validations studies for this test which are required prior to regulatory submission. The Company did not have another IVD test in the validation stage in fiscal 2014 and R&D efforts were focused on the development of other tests in the IVD pipeline and on paid development projects in the DTS business.

Corporate and general expenses include salaries and related expenses (including benefits and payroll taxes) of the Company other than salaries and related expenses paid to personnel engaged in research and development. Salaries and wages were \$554,000 for the year ended September 30, 2014 as compared to \$667,000 for the year ended September 30, 2013. The decrease in general and administrative salaries for the year ended September 30, 2014 as compared to the year ended September 30, 2013 is a result of reduction of one executive level position in June of 2013.

Corporate and general expenses also include general and administrative costs. Corporate and general expenses were \$458,000 in fiscal 2014 down from \$524,000 in fiscal 2013.

Professional and consulting fees were \$447,000 in the year ended September 30, 2014 as compared to costs of \$414,000 in the year ended September 30, 2013. The increase in professional and consulting fees was primarily related to increased investor relations costs as the Company focused on increasing investor and customer awareness.

Sales and marketing expense was primarily related to sales and marketing consultant fees and to travel related to selling activities. Sales and marketing expenses, excluding stock based compensation, totalled \$467,000 for the year ended September 30, 2013 compared to \$442,000 for the year ended September 30, 2013. Costs were consistent year over year; however the Company added one sales professional towards the end of the fiscal 2014.

#### Fourth Quarter Commentary

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

	September 30, 2014 (000s)	June 30, 2014 (000s)	March 31, 2014 (000s)	December 31, 2013 (000s)
Revenue	\$ 67	\$ 32	\$ 18	\$ 2
Net Loss	\$ 1,546	\$ 1,449	\$ 964	\$ 1,501
Net Loss Per Share	\$ (0.03)	\$ (0.03)	\$ (0.02)	\$ (0.03)
Weighted Average Shares	56,336	55,505	47,080	44,970

  

	September 30, 2013 (000s)	June 30, 2013 (000s)	March 31, 2013 (000s)	December 31, 2012 (000s)
Revenue	\$ -	\$ -	\$ -	\$ 3
Net Loss	\$ 1,553	\$ 1,740	\$ 1,351	\$ 1,563
Net Loss Per Share	\$ (0.03)	\$ (0.04)	\$ (0.03)	\$ (0.04)
Weighted Average Shares	44,952	43,206	39,826	39,826

During the fourth quarter of fiscal 2014 the Company continued to record revenue resulting from product and services sales in our DTS business. Revenue for the three months ended September 30, 2014 were \$67,000 compared to Nil for the same period last year. The revenue in the fourth quarter of fiscal 2014 includes revenue earned for the delivery of an automated prototype of a DNA-based pathogen detection test as well as for additional work contracted by one of our Global Pharma customers.

For the quarter-ended September 30, 2014, the Company recorded a net loss of \$1,546,000 (\$0.03 net loss per share) which is consistent with the net loss of \$1,553,000 (\$0.03 net loss per share) for the quarter-ended September 30, 2013. Per share values are based on the weighted average shares outstanding in the period. For the quarter-ended September 30, 2014 there was an average of 56,336,000 shares outstanding.

R&D expenditures, excluding amortization and stock based compensation, for the three months ended September 30, 2014 were \$757,000 compared to \$792,000 for the same period last year.

During the three months ended September 30, 2014 the Company continued development work for customers in its DTS business. The Company also focused some limited development efforts on two IVD tests. R&D costs were lower for the three months ended September 30, 2014 as compared to the same period in last year. In 2013 the Company incurred significant costs on the verification and validation of Celiac DGP. Validation of the celiac test was completed in the first fiscal quarter of 2014 and the Company has no other tests in the verification/validation stage resulting in lower development costs.

Corporate and general expenses include salaries and related expenses (including benefits and payroll taxes) of the Company other than salaries and related expenses paid to personnel engaged in research and development. Salaries and wages were \$165,000 for the quarter-ended September 30, 2014 compared to \$126,000 for the quarter-ended September 30, 2013. The increase mainly attributable to a final settlement reached with respect to one administrative position eliminated during the February 2014 layoff.

Corporate and general expenses also include general and administrative expenses which comprise occupancy costs, insurance costs, foreign exchange expenses, and other general operating costs. General and administrative expenses were \$119,000 for the three months ended September 30, 2014 compared to \$103,000 for the three months ended September 30, 2013. General and administrative costs are consistent period over period.

Professional consulting (legal, accounting, Board of Directors compensation, recruiting, administrative contractor, and investor relations) costs in the three months ended September 30, 2014 were \$177,000 compared to \$142,000 for the three months ended September 30, 2013. The increase in professional and consulting costs for the quarter ended September 30, 2014 compared to the same period last year is a result of investor relations initiatives pursued to increase customer and investor awareness.

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, totalled \$112,000 for the three months ended September 30, 2014 compared to \$143,000 for the three months ended September 30, 2013. Sales and marketing expenses were lower for the three months ended September 30, 2014 compared to the same periods in the previous year, primarily due executive level support of the business development and marketing strategies as part of the CEO transition in the fourth quarter of fiscal 2013.

Non-cash stock based compensation charges totalled \$26,000 for the three months ended September 30, 2014 (fiscal 2014 – \$201,000) compared to \$83,000 for the three months ended September 30, 2013 (fiscal 2013 – \$499,000). The related stock option issuances are described further in the Outstanding Capital Stock section that follows.

Operational expenses were partially offset by interest income earned on short-term investments of \$7,000 for the three months ended September 30, 2014 (fiscal 2014 –\$20,000) compared to \$6,000 for three months ended September 30, 2013 (fiscal 2013 – \$25,000). The Company invests its cash in variable term cashable government investment certificates and short-term money market deposits.

## **Sources and Uses of Cash**

Management expects losses to continue into fiscal 2015 as investment continues in product development and commercialization efforts for its pipeline of IVD and custom Ig\_plex test kits and platforms, as well as investment in sales and marketing. Management expects to reduce losses later in fiscal 2015 as it generates revenues and margin from a variety of Diagnostic Tools and Services' customers. The US FDA clearance of its IVD Celiac test could result in initial revenue from that product in fiscal 2015, further reducing overall losses.

The Company has funds sufficient to meet our anticipated cash requirements for approximately the next two months. The Company is actively reviewing its forecast expenditures, capital needs and financing options.

Operational activities for the year ended September 30, 2014 were financed by cash on hand.

At September 30, 2014, current assets were \$2,058,000 compared to \$1,724,000 at September 30, 2013. As at September 30, 2014 the Company has a \$1,625,000 working capital surplus compared to a surplus of \$1,270,000 at September 30, 2013.

Cash used in investing activities for the year ended September 30, 2014 was \$210,000 compared to \$429,000 for the year ended September 30, 2013. The Company continues to critically evaluate all capital purchases and is evaluating all patent and trademark expenditures. Investing activities focused on enhancing and maintaining the Company's patent and trademark portfolio, strategic laboratory equipment purchases and upgrading computer equipment.

During the year ended September 30, 2014 the Company completed a non-brokered private placement of 2,965,000 units of the Company at \$0.50 per unit for gross proceeds of \$1,483,000 and completed a public offering of 8,400,000 units for gross proceeds of \$4,200,000.

## **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 and the Annual Information Form dated December 16, 2014, you 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, its, his or her investment.

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

## Risks Related to Our Business and Strategy

***Our future capital needs are uncertain and we may need to raise additional funds in the future, which may not be available on a timely basis or on commercially reasonable terms.***

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

- maintain our current operations to address custom prototype projects and to deliver on contracts currently in place
- expand the commercialization of our products;
- manufacture our platforms in advance of placing them with our customers; and,
- further our research and development.

Our future funding requirements will depend upon many factors, including:

- development of new and existing products;
- market acceptance of our products;
- the cost of our research and development activities;
- the cost of potential licensing of technologies patented by others;
- the cost of filing and prosecuting patent applications;
- the cost and timing of regulatory clearances or approvals;
- the cost and timing of establishing additional sales, marketing and distribution capabilities;
- the cost and timing of establishing additional technical support capabilities;
- the effect of competing technological and market developments;
- the cost of defending, in litigation or otherwise, any claims that we infringe third party patents or violate other intellectual property rights; and
- the extent to which we acquire or invest in businesses, products and technologies, although we currently have no commitments or agreements relating to any of these types of transactions.

If we raise additional funds by issuing equity securities, our shareholders may experience dilution. Debt financing, if available, may involve covenants restricting our operations or our ability to incur additional debt. 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.

Our future success depends upon our ability to expand our customer base and introduce new products and services.

***We have incurred losses since inception, and we expect to continue to incur losses for the foreseeable future.***

We have a limited operating history and have incurred significant losses in each fiscal year since our inception, including net losses of \$3.8 million, \$5.9 million, \$8.1 million, \$10.7 million \$6.3 million \$6.2 million and \$5.5 million during fiscal 2008, 2009, 2010, 2011, 2012, 2013, and 2014 respectively. As of September 30, 2014, we had an accumulated deficit of \$62.3 million. These losses have resulted principally from costs incurred in our research and development programs and from our selling, general and administrative expenses. We expect to continue to incur operating and net losses and negative cash flow from operations, which may increase, for the foreseeable future due in part to anticipated increases in expenses for research and product development and expansion of our sales and marketing capabilities. We anticipate that our business will generate operating losses until we successfully implement our commercial development strategy and generate significant additional revenues to support our level of operating expenses. Because of the numerous risks and uncertainties associated with our commercialization efforts and future product development, we are unable to predict when we will become profitable, and we may never become profitable. Even if we do achieve profitability, we may not be able to sustain or increase our profitability.

***Market competition and technological advances of similar diagnostics products could reduce the attractiveness of our products or render them obsolete.***

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 our current competitors have significantly greater name recognition, greater financial and human resources, broader product lines and product packages, larger sales forces, larger existing installed bases, larger intellectual property portfolios and greater experience and capabilities in researching, developing and testing products, in obtaining FDA and other regulatory approvals or clearances, and in manufacturing, marketing and distribution, than we have. For example, companies such as Bio-Rad Laboratories Inc., Phadia AB, Axis-Shield plc, and INOVA Diagnostics Inc. have products that compete in certain segments of the market in which we sell our products, including immunoassays. In addition, a number of other companies and academic groups are in the process of developing novel products and technologies for diagnostics markets.

Our competitors may be able to respond more quickly and effectively than we can to new or changing opportunities, technologies, standards or customer requirements. In light of these advantages, even if our technology is more effective than the product or service offerings of our competitors, current or potential customers might accept competitive products and services in lieu of purchasing our technology. 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. We may not be able to compete effectively against these organizations. Increased competition 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 results of operations.

***If our products fail to achieve and sustain sufficient market acceptance, our revenue will be adversely affected.***

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 test 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.

***We are subject to complex regulatory compliance requirements and the failure to obtain, or the withdrawal of, regulatory clearance or approval for our products could adversely affect our ability to market our products and/or require us to incur significant costs to comply with such requirements.***

We operate in a highly regulated industry and we are subject to the authority of certain regulatory agencies, including Health Canada, the FDA, European Conformity (CE) and applicable health authorities in other countries, with regard to the development, testing, manufacturing, marketing and sale of our diagnostic products. The process of obtaining such clearances or approvals can be costly and time-consuming, and if we are unable to obtain on a timely basis or to maintain regulatory clearances or approvals, it would have a material adverse effect on our business. Clearance by regulatory authorities can be suspended or revoked, or we could be fined, based on a failure to continue to comply with applicable standards. Any failure to obtain (or significant delay in obtaining) or maintain applicable regulatory clearances or approvals (or, to a lesser extent, approval of applicable health authorities in other countries) for our new or existing products could materially affect our ability to 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.

We must manufacture products in compliance with regulatory requirements, in sufficient quantities and on a timely basis, while maintaining product quality and acceptable manufacturing costs. If we or our suppliers are unable to manufacture or contract for such capabilities on acceptable terms, our plans for commercialization could be materially adversely affected.

Our manufacturing facilities are subject to periodic regulatory inspections by the regulatory agencies and these facilities are subject to quality standards requirements of the applicable regulatory authorities. We, or our contractors, may not satisfy such regulatory or standards requirements, and any failure to do so may have a material adverse effect on our business, financial condition and results of operations.

***We may not be able to develop new products or enhance the capabilities of our existing diagnostics products to keep pace with 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 develop new products with improved performance and cost effectiveness in existing and new markets. New technologies, techniques or products could emerge that might offer better combinations of price and performance than our current or future product lines. It is critical to our success for us to anticipate changes in technology and customer requirements and to successfully introduce new, enhanced and competitive technology to meet our prospective customers' needs on a timely basis.

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. We cannot guarantee that we will be able to maintain technological advantages over emerging technologies in the future. While we plan to continue to make improvements to our current and future cleared or approved and marketed diagnostic processing equipment and consumable tests, we may not be able to successfully implement these improvements. If we fail to keep pace with emerging technologies, demand for our products will not grow, and our business, revenue, financial condition and operating results could suffer materially. Even if we successfully implement some or all of these planned 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 of diagnostic products requires significant testing and investment and may not result in commercially viable products within the timeline anticipated, if at all.***

New diagnostic products, and improvements to existing diagnostic products, require significant research, development, testing and investment prior to any final commercialization. Our business depends upon 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 test menu of tests to potential customers. To date, we have obtained regulatory approval for only a few diagnostic tests.

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 or enhance existing products would have a material adverse effect on our business and results of operations. If we are unable to successfully develop these products, accomplish such improvements, receive applicable regulatory clearances or approvals, produce the products in commercial quantities at reasonable costs, or successfully market the products, it 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.

***Our future success depends upon our ability to expand our customer base and introduce new products and services.***

Our success will depend upon our ability to gain acceptance, and then increase our market share among our customers, attract additional customers outside of our initial target markets, and bring to market new products and services. Attracting new customers and introducing new products and services requires substantial time and expense. For example, it may be difficult to identify, engage and market to customers who are unfamiliar with the benefits of our products and services. Any failure to establish and expand our existing customer base or launch new products or services would adversely affect our ability to increase our revenues.

***We have limited experience in marketing, selling and distributing our products, and we need to expand our internal and external sales and marketing force and distribution capabilities to successfully commercialize and sell our products.***

As we are in the early stages of commercializing and marketing our products, we have limited experience in marketing, selling and distributing our products. We may not be able to market, sell

and distribute our products effectively enough to support our planned growth. 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 upon 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. Our ability to market our products effectively will depend, in part, upon our ability to convince laboratories that our products will deliver accurate patient results in less time and with significantly reduced labour, consumables and other costs. 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.

***We rely on strategic partnerships for research and development and commercialization of our products.***

We have entered into and may continue to enter into strategic partnerships with a number of medical institutions. For example, we have entered into strategic agreements with The University of North Carolina at Chapel Hill, the Cleveland Clinic, Beth Israel Deaconess Medical Center, Hospital Clinic De Barcelona, and University Hospital Maastricht. If our strategic partners were to change their business strategies or development priorities, they may no longer be willing or able to participate in such strategic partnerships which could have an adverse effect on the timing of our future development efforts. In addition, we may not control the strategic partnerships in which we participate. We may also have certain obligations with regard to our strategic partnerships, in addition to the obligation to pay money, such as an obligation to publish the results of research.

***We depend upon key suppliers for some of the components and materials used in our platform technologies and our microarrays, and the loss of any of these suppliers could harm our business.***

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 is a limited number of suppliers who can manufacture the highly specialized equipment that forms a part of our systems.

Our first set of tests being commercialized requires a highly specific mono-layer coating on the glass surface which is used to bond each of the microarray “spots”. We have worked closely with these manufacturers to extend the capabilities of their standard products to support the unique needs of our platform technologies and microarray devices. 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.

Our reliance on these suppliers also subjects us to other risks that could harm our business, including the following:

- we may be subject to increased component costs;
- we may not be able to ensure that any component that we change performs in a substantially similar manner to the existing component;

- we may not be able to obtain adequate supply in a timely manner or on commercially reasonable terms;
- our suppliers may make errors in manufacturing components that could negatively affect the efficacy of our systems or cause delays in shipment of our systems; and
- our suppliers may encounter financial hardships unrelated to our demand for components, which could inhibit their ability to fulfill our orders and meet our requirements.

We may not be able to quickly establish additional or replacement suppliers, particularly for our single source components. 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.

***Future legislative or regulatory changes to the healthcare system, including reimbursement, may adversely affect our business.***

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 due to medical coverage or reimbursement limits. 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. These healthcare management organizations and third party payors are increasingly challenging the prices charged for medical products and services. The containment of healthcare costs has become a priority of governments. Accordingly, our potential products may not be considered cost effective, and reimbursement to the ultimate patient may not be available or sufficient to allow us to sell our products on a competitive basis.

***We rely on certain key personnel and our ability to successfully grow our business would be adversely affected by their departure from our company.***

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 Vice President of Research and Development, Dr. Jaymie Sawyer. Retaining these key personnel and recruiting additional qualified personnel in the future will be critical to our success. We believe there are only a limited number of individuals with the requisite skills to serve in many of our key positions. Competition for qualified personnel in the diagnostics industry is intense and recruiting and retaining qualified personnel with experience in our industry is very difficult. We compete for key personnel with other medical equipment and software manufacturers and technology companies, as well as universities and research institutions.

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 scientific or technical staff, we could experience significant delays in, or we could be unable to, complete the development and commercialization of our products or achieve our other business objectives, and such a development could require our management to divert its attention to transition matters and identification of suitable replacements, if any. Such a development could have a material adverse effect on our business, financial condition and results of operations.

We do not maintain, and do not intend to obtain, key employee life insurance on any of our personnel.

A portion of our compensation to our key employees is in the form of stock option grants. A prolonged decline in our share price could make it difficult for us to retain our employees or recruit additional qualified personnel.

***If we cannot provide quality technical support, we could lose customers and our operating results could suffer.***

The placement of our products and the introduction of our technology into our customers' existing operations and on-going customer support can be complex. Accordingly, we need highly trained technical support personnel. To effectively support new customers, we will need to substantially expand our technical support staff. If we are unable to attract, train or retain the number of highly qualified technical services personnel that our business will require, our business, financial condition and results of operations will suffer.

***We may experience development or manufacturing problems or delays that could limit the growth of our revenue or increase our losses.***

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 would 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 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.

***Our products could have unknown defects or errors, which may give rise to claims against us and adversely affect market adoption of our systems.***

Our products utilize complex technology 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. We may determine to correct any defects or errors in response to customer concerns, in order to preserve customer relationships, and to help foster continued adoption and use of our systems. 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 the suppliers, or we, use defective materials or workmanship in the manufacturing process, the reliability and performance of our products will be compromised.

If our products contain defects, we may experience:

- a failure to achieve market acceptance or expansion of our product sales;
- loss of customer orders and delay in order fulfillment;
- damage to our brand reputation;
- increased cost of our warranty program due to product repair or replacement;
- product recalls or replacements;
- inability to attract new customers;

- diversion of resources from our manufacturing and research and development departments into our service department; and
- legal claims against us, including product liability claims, which could be costly and time consuming to defend and result in substantial damages.

The occurrence of any one or more of the foregoing could negatively affect our business, financial condition and results of operations.

***Our future financial results may be adversely affected by 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**

***Our ability to protect our intellectual property and proprietary technology through patents and other means is uncertain.***

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. To the extent our intellectual property, including licensed intellectual property, offers inadequate protection, or is found to be invalid or unenforceable, we are exposed to a greater risk of direct competition. If our intellectual property does not provide adequate protection against our competitors' products, our competitive position could be adversely affected, as could our business, financial condition and results of operations.

We may be involved in lawsuits 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 that could require us to spend significant time and money and could prevent us from selling our products or services or impact our share price.

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

***We expect that our share price will fluctuate significantly, and you may not be able to resell your common shares at or above the current price.***

Our common shares are listed for trading on the TSX Venture Exchange ("TSXV"). We cannot predict the extent to which investor interest in our company will lead to the development of an active trading market on the TSXV, or how liquid that market might become. If an active trading market does not develop, you may have difficulty selling any of our common shares that you buy. The market price of our common shares on the TSXV, like the share prices of many publicly traded life sciences companies, has been highly volatile, and the trading price of our common shares may remain volatile in response to various factors, some of which are beyond our control.

***We have never paid dividends on our common shares, and we do not anticipate paying any cash dividends in the foreseeable future.***

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. Dividends on our common shares are declared at the discretion of our board of directors and will depend on our results of operations, capital requirements, financial condition, prospects, contractual arrangements and other factors that our board determines is relevant.

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 did not earn significant revenues from its test kits or its diagnostic platforms. Management believes that it may generate revenues from a variety of Diagnostic Tools and Services customers in fiscal 2014; this is subject to certain risks including the continued success of the development program. The continuation of the Company's research, development and commercialization activities along with investment in marketing and sales is dependent upon 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 financing 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 will be offered.

## Outstanding Capital Stock

As at December 16, 2014, there were 56,336,058 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 16, 2014:

<b>Number of Warrants</b>	<b>Purchase Price</b>	<b>Weighted average time to maturity</b>
1,140	\$5.00	0.65 years
5,784	\$2.50	0.99 years
5,126	\$1.10	0.37 years
513	\$0.75	0.37 years
11,365	\$0.65	1.26 years
885	\$0.50	1.25 years
<b>24,813</b>		

The Company had the following stock options outstanding under the Plan at December 16, 2014:

<b>Number of Options</b>	<b>Range of Exercise Prices</b>	<b>Weighted average time to maturity</b>
1,800	\$0.35 - 1.31	3.64 years
497	\$1.32 - 2.28	2.02 years
303	\$2.29 - 3.26	0.69 years
<b>2,600</b>		

## Off-Balance Sheet Arrangements

The Company has no off-balance sheet arrangements.

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

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

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

### **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 ten 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 expensed as incurred or deferred if they meet the criteria for deferral under IFRS and are expected to provide future benefits with reasonable certainty.

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

The Company offers a share option plan for its employees, officers and directors. 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 there of 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.

In situations where non-employee stock-based compensation is issued and some or all of the goods or services received by the entity as consideration cannot be measured reliably, they are measured at the fair value of the stock-based payment.

### **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.

Significant areas requiring the use of management estimates relate to the determination of the useful lives of property and equipment and patents and trademarks for amortization purposes and impairment of same, valuation of ITCs recoverable, valuation of stock options and warrants and recognition of deferred tax assets.

## **RECENT ACCOUNTING PRONOUNCEMENTS**

### **IFRS 9 Financial Instruments**

In October 2010, the IASB issued IFRS 9, Financial Instruments (IFRS 9). IFRS 9, which replaces IAS 39, Financial Instruments: Recognition and Measurement, establishes principles for the financial reporting of financial assets and financial liabilities. The effective date for IFRS 9, which is to be applied retrospectively, is for annual periods beginning on or after January 1, 2018. The Company is assessing the impact of this new standard on its consolidated financial statements.

### **IAS 38 Intangible Assets and IAS 16 Property Plant and Equipment**

In May 2014, the IASB issued amendments to these standards to introduce a rebuttable presumption that the use of revenue-based amortization methods is inappropriate. The amendment is effective for annual periods beginning on or after January 1, 2016 with earlier adoption permitted. The Company is currently assessing the impact of this new standard on its consolidated financial statements.

### **IFRS 15 Revenue Recognition**

In May 2014, the IASB issued IFRS 15 Revenue from Contracts with Customers. IFRS 15 replaces the detailed guidance on revenue recognition requirements that currently exists under IFRS. IFRS 15 specifies the accounting treatment for all revenue arising from contracts with customers, unless the contracts are within the scope of other IFRS guidance. The standard also provides a model for the measurement and recognition of gains and losses on the sale of certain non-financial assets that are not an output of the Company's ordinary activities.

Additional disclosure is required under the standard, including disaggregation of total revenue, information about performance obligations, changes in contract asset and liability account balances between periods, and key judgments and estimates. The standard is effective for annual periods beginning on or after January 1, 2017; early application is permitted either following a full retrospective approach or a modified retrospective approach. The modified retrospective approach allows the standard to be applied to existing contracts beginning the initial period of adoption and restatements to the comparative periods are not required. The Company is required to disclose the impact by financial line item as a result of the adoption of the new standard. The Company is currently assessing the impact of this new standard on its consolidated financial statements.

## **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, 2014;
- (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 quarter-ended September 30, 2014; 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.