



## **SQI DIAGNOSTICS INC.**

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

**September 30, 2013**

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

*This Management's Discussion and Analysis ("MD&A") covers the audited financial statements for years ended September 30, 2013 and 2012. The annual audited financial statements for the year ended September 30, 2013 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 January 27, 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" 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 expected future losses and accumulated deficit levels;*
- our requirement for, and our ability to obtain, future funding on favourable terms or at all;*
- market competition and technological advances of competitive products;*
- 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;*
- 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 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**

SQI Diagnostics Inc. is an innovator in multiplexed microarray diagnostics and life sciences tools. Our goal is to become a leader in the development and commercialization of microarray and multiplexed blood tests to enable simultaneous measurement of important molecules like proteins, antibodies and inflammatory markers. We do this by offering our customers comprehensive “turnkey” solutions that allow them to replace current multiple tests that are very labour intensive and expensive with our multiplex tests and diagnostic platforms. Customers value multiplex tests from SQI because they combine multiple tests that they use in a particular application with a single multiplex test providing all of the results and the test performance they currently expect. SQI’s multiplex tests increase the efficiency and ease of bioanalytical, immunogenicity and diagnostic testing. Our advanced diagnostic platforms and software are used to greatly reduce the time and effort consumed in test development. This reduces the overall cost of delivery for both SQI and our customers. Our multiplex tests and diagnostic platform together form a very powerful tool for the design, commercialization and execution of blood testing in clinical trials for drug development markets.

The Company is engaged in two principal and integrated lines of business:

1. **Diagnostic Tools and Services (DTS)** is focused primarily on drug development customers including Pharmaceutical companies and Contract Research Organizations (CROs) and includes test design, development and validation services resulting in custom multiplex tests. The services provided then result in the manufacture and sale of the custom kits for use in the customer’s pre-clinical and clinical drug trials. In some cases SQI would also provide sample analysis at SQI, as a service for lower volume samples.

2. **Multiplexed IVD products** targeting protein and antibody biomarkers in autoimmune and other immunology markets that are developed validated and manufactured by the Company for direct marketing and sales to reference labs.

Our proprietary microarray tests and automated diagnostic platforms have the potential to change the way pharmaceutical companies design and conduct antigen, protein and antibody testing. In using SQL's custom Ig\_plex™ tests and sqid-analyzers, pharmaceutical companies enjoy many of the benefits and processes incorporated into our FDA-cleared IVD tests and analyzers. This provides them or their CROs the confidence to test responses to their biosimilar and innovator drugs in one multiplexed test, decreasing the number of studies required and potentially shortening development times to regulatory filing. Shortening the time to regulatory filing would 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.

Our technology meets or exceeds all FDA guidance for EMA immunogenicity and biosimilar test guidelines. These applications for our technology open up a new and growing market for SQL, as regulatory focus on immunogenicity testing of biopharmaceutical drug offerings increases.

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 and sub-classes of antibodies as well as human proteins including protein-based drugs. 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, capable of providing multiple biomarker measurements in each single test array, have the potential to increase a laboratory's throughput with significantly less labour, consumables and other costs. Our greatest value proposition is the ability to greatly reduce the effort and time to complete certain aspects of clinical testing in a drug development program or IVD testing in a reference laboratory.

### **Platforms**

Our sqidlite™ Bench-Top Diagnostic System (sqidlite), launched at the American Association of Pharmaceutical Scientists (AAPS) Annual Meeting and Exposition in October of 2012, offers laboratories of all sizes flexible, configurable, fully automated workflow solutions from dilutions through reporting to run protein and antibody multiplexed immunoassays. This bench-top system will be able to process multiple sizes of microarray devices from single 8-well strips up to a single 96-well microarray plate. 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, which provides significant cost savings and other benefits over existing technologies. The incremental cost savings of tests run on our fully-automated platform versus existing technologies increase as the complexity of the test increases.

Our sqid-X™ System is a semi-automated bench-top platform that incorporates all of SQL's technology with the exception of automated fluidics handling and is targeted at earlier stage, lower volume customers and those who intend to complete custom Ig\_plex assay development work at their sites.

### **Assays**

Our Ig\_plex microarrays have the ability to accurately measure multiple biomarkers, including but not limited to antibodies, their isotypes and subclasses of the isotypes in a single test, all while using less patient serum than established tests. Additionally, our microarray technology requires fewer steps than traditional methods. These key features may increase the predictive value of the test. The increased predictive value of the test may enable the healthcare provider to choose

a treatment plan earlier in the course of the disease. Pharmaceutical customers also benefit from our antibody isotyping and subclass multiplexing by receiving more robust data on immunogenic responses to their in-development drugs than previously available. These same customers also stand to benefit through the cost and time savings from multiplexing which could reduce their time to market improving, their bottom line results.

Our proprietary multiplex assay development process and microarray manufacturing capabilities, combined with our automated systems, are designed to significantly reduce the complexity and cost to our customers to commercialize microarray tests, or to develop in-house research use only (RUO) bioanalytical tests to capture and measure their target biomarkers.

The Company is focussing on leveraging its existing technologies and its IVD pedigree to develop custom Ig\_plex tests that can be processed on our systems and address the needs of the large pharmaceutical drug development market. The status of the Company's commercialization and development efforts are discussed below.

**COMMERCIALIZATION AND DEVELOPMENT ACTIVITIES – 2013 FISCAL YEAR**

The Company has been focussing on arranging and completing many targeted sales and business development initiatives with a large number of pharmaceutical and vaccine companies currently using single-plex immunogenicity tests in drug development and CROs that service the immunogenicity testing needs of pharmaceutical companies that outsource their bioanalytical and immunogenicity testing. The Company has developed various commercial relationships during the fiscal year and subsequent to the year end. The names of certain customers or potential customers have been omitted owing to confidentiality agreements with these entities.

<b>Commercialization and Development Activities Since October 1, 2012</b>
<p>In the first quarter of 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 will be paid to build a 6-plex anti-drug antibody (ADA) assay to detect and measure immunogenic responses to a drug in the customer's extensive drug pipeline. In January of 2014 a further contract was established with this customer to test a small sub-set of the customer's pre-clinical samples.</p> <p>Also in the first quarter of fiscal 2014, the Company entered into an agreement to develop a multiplexed ADA assay for Isis Pharma. The Company believes that successful development will lead to adoption by Isis's CRO of the SQI-developed test in clinical testing and could result in material revenues.</p> <p>Management believes that successful completion of the customer projects above would significantly increase the probability of winning additional custom ADA and other biomarker business within our growing customer base.</p> <p>The Company is in negotiations with several other potential customers to commence the development of paid evaluation assays. The Company believes that some or all of these negotiations will result in additional DTS revenue in the first half of calendar 2014.</p>
<p>On October 8, 2013 Bristol-Myers Squibb (BMS) gave a key-note presentation and presented a poster that highlighted the results of a custom built immunogenicity assay for a BMS drug, on four different animal species at the Bioassay and Bioanalytical Method Development Conference in Berkley California. The poster and presentation demonstrated SQI's superior performance as compared to a standard ELISA tests as well as another competitive multiplexing technology.</p>
<p>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 anti-drug-antibody ("ADA") assay to detect and quantify the immune response in four animal species to a new class of drug. Management believes that the customer will commercially adopt the SQI technology in future clinical trials.</p>

During the year ended September 30, 2013 the Company entered into a master services agreement with another global pharmaceutical company (Global Pharma 2). The agreement governed the development and evaluation of a 21 biomarker ADA assay to measure the immune responses in clinical trials to the customer's in-development biologic drug. Major development milestones have been achieved to date on this project and the Company believes that it is well positioned to win on-going revenue and to deliver test kits and a platform(s) for use in testing clinical samples in the first half of calendar 2014.

During the year ended September 30, 2013 Global Pharma 2 also expressed interest in evaluating the Company's 8-plex cytokine assay. The Company made significant progress on the commercial demonstration and delivered a sqid-X platform to the customer's site to enable evaluation of the Ig\_plex Cytokine assay in the first half of fiscal 2014. Management believes that successful evaluation will result in a commercial contract with Global Pharma 2 for the Company's cytokine product.

On January 24<sup>th</sup>, 2013, the Company signed a collaboration agreement with Algorithme Pharma ("Algorithme") to develop an assay targeted at immunogenicity testing of heparin and heparin-based low molecular weight biosimilar compounds ("HIT assay"). The proof-of-concept was developed and SQI and Algorithme began jointly marketing the shelf ready assay. These marketing efforts included, among others, presenting the results of the proof-of-concept studies at the 14th Annual Immunogenicity for Biotherapeutics Conference in Baltimore held 18-20 March, a webinar titled "A Multiplexed Approach for Immunogenicity Assessment Using the New sqidlite™ System: Case Study Analysis" held on July 11, 2013, and a presentation at the Bioanalysis and Bioanalytical Method Development Conference in Berkley California on October 8, 2013. Algorithme and the Company continue to expand their co-marketing relationship and in 2014 the Company expects that one or more of its customers will outsource production of testing clinical samples using SQI's products to Algorithme.

The new sqid-X platform, a semi-automated multiplexed immunoassay platform, was developed during the year. The sqid-X is a less expensive platform for customers with lower test volumes or for use by customers in the early development stage prior to transitioning to a sqidlite platform. This platform is being used in the verification stage for our IVD assays and is fully commercial for DTS customers.

Verification work on Ig\_plex Celiac DGP is complete and, the Company is moving to complete validation. The Company intends to complete regulatory filings early in the first quarter of calendar 2014.

The Company's current focus is to deliver on the customer-targeted proof-of-concept assays to generate near-term revenues. The Company is delivering on this goal and has demonstrated to its first target customers, Global Pharma 1, Global Pharma 2, Isis Pharma, and Global Pharma 3 that it can deliver the custom Ig\_plex assays specific to their drug targets within agreed upon timelines. The Company will advance its pipeline of IVD assays; however, the Company will prioritize projects in favour of those with near-term revenue prospects.

The status of each component of our development program is summarized in the table below:

DEVELOPMENT STATUS - IVD						
PRODUCT	STAGE OF DEVELOPMENT					
	Candidate Panel	Proof-of-Concept	Assay Development	Automation	Validation	Approval/Clearance
IgX PLEX RA (Qualitative) (1)						
IgX PLEX RA (Quantitative) (2)						
IgX PLEX Celiac (Qualitative) (1)						
IgX PLEX Celiac (Quantitative) (2)						
Ig_plex Celiac DGP (Quantitative)*						
Ig_plex Vasculitis						
Ig_plex RA (Quantitative) (3) ON HOLD						
Ig_plex Lupus ON HOLD						
Ig_plex IBD/Crohn's ON HOLD						

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

\* Validation completed subsequent to year end

DEVELOPMENT STATUS – Custom Ig_plex and Immunogenicity						
PRODUCT	STAGE OF DEVELOPMENT					
	Candidate Panel	Proof-of-Concept	Assay Development	Automation	Validation	Ready to Commercialize
Cytokines 8 plex (RUO)						
Heparin Immunogenicity Assay						
Global Pharma 1						
Global Pharma 2						
Isis Pharmaceuticals*						
Global Pharma 3*						

\* project commenced subsequent to year end

## 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 million.

Each unit consists of one common share and one common share purchase warrant. Each common share purchase warrant entitles the holder to purchase one common share at a price of \$0.65 for a period of two years from the date of issuance.

In connection with the private placement, the Company paid a finder's fee equal to 7% of the gross proceeds and issued 296,500 compensation warrants exercisable for a period of two years for the Closing of the Private Placement. Each warrant is exercisable into one common share and one warrant at price of \$0.50. Each underlying warrant is exercisable into one common share at a price of \$0.65 for a two year period.

As a result of the financing the Company now has funds sufficient to meet our anticipated cash requirements for approximately the next 3 months. The Company is reviewing its forecast expenditures, capital needs and financing options.

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.

On May 2, 2013 the Company completed a non-brokered private placement of 5,126,044 units of the Company at \$0.75 per unit for gross proceeds of \$3,845,000. 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 \$1.10 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 \$1,162,000 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 \$0.53; dividend yield 0%; risk free interest 0.95%; volatility 115%; 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 \$269,000 and issued 512,604 compensation warrants exercisable for 24 months from the closing of the private placement. Each compensation warrant is exercisable into one common share and one warrant at a price of \$0.75. Each underlying warrant included in the compensation warrant is exercisable into one common share at a price of \$1.10 for a two year period from the date of the private placement. The fair value of the compensation warrants was estimated at \$331,000 using the Black-Scholes pricing model with the following assumptions: share price \$1.00; dividend yield 0%; risk free interest 0.95%; volatility 115%; 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 \$628,000.

On July 29, 2013 the Company received approval to extend the expiry of 1,140,000 warrants with an expiry of August 12, 2013 and an exercise price of \$5.00 to August 12, 2015. 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 \$0.69; dividend yield 0%; risk free interest 1.25%; volatility 127%; and an expected life of 2 years. Expected volatility is based on historical volatility. As a result of the extension \$203,000 was recorded in warrant capital with a corresponding reduction in contributed surplus.

Subsequent to year end, 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. 86,040 warrants with an expiry of October 26, 2013 expired unexercised.

## **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 10 years on a straight-line basis. Patents and trademarks are recorded net of impairment losses, if any. Research costs are charged to operations in the period in which they are incurred. Development costs are expensed as incurred or deferred if they meet the criteria for deferral under International Financial Reporting Standards and are expected to provide future benefits with reasonable certainty.

At September 30, 2013, the Company was developing two customer-targeted proof-of-concept multiplexed immunogenicity assays, the multiplexed assay targeted at immunogenicity testing of heparin and heparin-based low molecular weight biosimilar compounds (HIT Assay), Ig<sub>plex</sub> diagnostics assays for celiac, vasculitis and an 8-plex cytokine assay. While not in active development, other assays in the development pipeline include lupus (SLE), Crohn's (IBD) and the second generation, fully quantitative Ig<sub>plex</sub> RA assay. Deferral criteria have not been met, and accordingly, all development costs have been expensed in the period.

### **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 International Financial Reporting Standards 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. This new standard is effective for annual periods beginning on or after January 1, 2015, with earlier application permitted. The Company is assessing the impact of this new standard on its consolidated financial statements.

### **IFRS 10 Consolidated Financial Statements and IAS 27 Separate Financial Statements**

In May, 2011, the IASB issued IFRS 10, Consolidated Financial Statements (IFRS 10) and IAS 27 Separate Financial Statements (IAS 27). IFRS 10 and the amended IAS 27 together replace IAS 27 Consolidated and Separate Financial Statements. IFRS 10 establishes the principles for the presentation and preparation of consolidated financial statements when an entity controls one or more other entities. IAS 27 prescribes the accounting and disclosure requirements for investments in subsidiaries, joint ventures and associates when an entity prepares separate financial statements. These standards are effective for annual periods beginning on or after January 1, 2013, with earlier application permitted. The Company is assessing the impact of this new standard on its consolidated financial statements.

### **IFRS 13 Fair Value Measurement**

In May, 2011, the IASB issued IFRS 13 Fair Value Measurement (IFRS 13). IFRS 13, which is to be applied prospectively, is effective for annual periods beginning on or after January 1, 2013, with earlier application permitted.

IFRS 13 defines fair value, provides a framework for measuring fair value and includes disclosure requirements for fair value measurements. IFRS 13 will be applied in most cases when another IFRS requires (or permits) fair value measurement. The Company is assessing the impact of this new standard on its consolidated financial statements.

## SELECTED FINANCIAL INFORMATION

The table below summarizes annual financial information for the fiscal years ended September 30, 2013 and 2012.

	Year ended September 30, 2013 (000s)	Year ended September 30, 2012 (000s)
Revenue	\$ 3	\$ 12
Net Loss	\$ 6,207	\$ 6,311
Net Loss Per Share	\$ (0.15)	\$ (0.17)
Weighted Average Shares	41,961	37,406

The net loss for the year ended September 30, 2013 was \$6,207,000 (\$0.15 net loss per share) as compared to \$6,311,000 (\$0.17 net loss per share) for the year ended September 30, 2012. The net loss for the year ended September 30, 2013 is consistent with the loss for the year ended September 30, 2012. In early fiscal 2012 the Company implemented a business restructuring which reduced personnel costs and streamlined product development to focus on those products with near term revenue generating potential. Since this time the Company has focused on developing a pipeline of Diagnostics Tools and Services customers and delivering proof-of-concept assays for target customers. In fiscal 2013 the company completed and delivered three proof-of-concept assays and expects that the projects will lead to commercial relationships with these customers.

Revenue for the year ended September 30, 2013 was \$3,000 versus \$12,000 for the year ended September 30, 2012. Revenue in the year ended September 30, 2013 was from product sales in our DTS business to one of our vendors. Revenues in the fiscal 2012 year resulted from the sale of the QuantiSpot RA test kits.

Research and development (R&D) costs, excluding amortization, stock based compensation and the SR&ED Investment Tax Credit (SR&ED ITC) were \$3,320,000 for the year ending September 30, 2013 compared to \$3,561,000 for the year ending September 30, 2012. The lower R&D costs in fiscal 2013 were a result of the Company's focus on advancing its Ig\_plex celiac assay and on developing proof-of-concept assays for customers in the Diagnostics Tools and Services business. The collaboration agreements for the proof-of-concept assays have, in some cases, required these potential customers to provide certain reagents and antibodies, off-setting the Company's research and development costs. In fiscal 2012 the Company's focus was on IVD assays which required higher laboratory and validation costs.

The SR&ED ITC was \$300,000 for the year ended September 30, 2013 compared to \$504,000 for the year ended September 30, 2012. In fiscal 2012 the Company finalized an audit of the 2008, 2009 and 2010 SR&ED claims which resulted in the settlement of amounts related to those years in addition to the 2012 claim.

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 \$667,000 for the year ended

September 30, 2013 as compared to \$833,000 for the year ended September 30, 2012. The decrease in general and administrative salaries for the year ended September 30, 2013 as compared to the year ended September 30, 2012 is a result of the business realignment in fiscal 2012 when temporary reductions were made to administrative salaries. A bonus and payment of deferred salaries was recorded in 2012 for those that had salary deferrals. Salaries returned to normal levels in July of 2012 and through the current period.

Corporate and general expenses also include general and administrative costs. The Company continued to maintain the level of expenditures on corporate and general expenses with costs of \$524,000 in fiscal 2013 as compared to \$545,000 in fiscal 2012.

Professional and consulting fees were \$414,000 in the year ended September 30, 2013 consistent with costs of \$423,000 in the year ended September 30, 2012.

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 \$442,000 for the year ended September 30, 2013 compared to \$273,000 for the year ended September 30, 2012. The increase of \$169,000 was primarily a result of the addition of a senior sales contractor in June of 2012 and throughout fiscal 2013 and increased expenditures on conferences, travelling and marketing as the Company focuses on creating and developing sales opportunities for its Diagnostic Tools and Services business.

## SELECTED FINANCIAL INFORMATION

### Fourth Quarter Commentary

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

	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

  

	September 30, 2012 (000s)	June 30, 2012 (000s)	March 31, 2012 (000s)	December 31, 2011 (000s)
Revenue	\$ -	\$ -	\$ 8	\$ 4
Net Loss	\$ 1,727	\$ 1,584	\$ 1,350	\$ 1,650
Net Loss Per Share	\$ (0.04)	\$ (0.04)	\$ (0.04)	\$ (0.05)
Weighted Average Shares	39,822	37,877	36,280	35,637

For the quarter-ended September 30, 2013, the Company recorded a net loss of \$1,553,000 (\$0.03 net loss per share) compared to a net loss of \$1,727,000 (\$0.04 net loss per share) for the quarter-ended September 30, 2012.

The net loss for the three months ended September 30, 2013 was lower compared to the three months ended September 30, 2012. The Company continued to control personnel and other administrative costs and to focus on development projects for Diagnostic Tools and Services customers that have the potential to evolve into commercial projects. The Company had three DTS projects in the quarter ended September 30, 2013.

R&D expenditures, excluding amortization and stock based compensation for the quarter-ended September 30, 2013 were \$792,000 compared to \$819,000 for the quarter-ended September 30, 2012. Costs were lower in the fourth quarter of fiscal 2013 as compared to the fourth quarter of 2012 due the increased emphasis on custom Ig<sub>plex</sub> projects which result in lower R&D personnel and laboratory costs than is typically required for the development of IVD tests. In the fourth quarter of fiscal 2013 the Company was moving the celiac assay through final verification studies and had three DTS projects in development. In the fourth quarter of fiscal 2012 the Company was focussing on the celiac and vasculitis assays as well as its initial immunogenicity proof-of-concept assay.

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 \$126,000 for the quarter-ended September 30, 2013 compared to \$190,000 for the quarter-ended September 30, 2012. The

decrease in general and administrative salaries for the three months ended September 30, 2013 as compared to the three months ended September 30, 2012 is a result of the executive promotions announced in June of 2013 which resulted in the elimination of one executive level position.

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 \$103,000 for the three months ended September 30, 2013 compared to \$133,000 for the three months ended September 30, 2012. General and administrative expenses for the three months ended September 30, 2013 are consistent with the expenses for the three months ended September 30, 2012.

Professional consulting (legal, accounting, Board of Directors compensation, recruiting, administrative contractor, and investor relations) costs in the three months ended September 30, 2013 were \$142,000 compared to \$178,000 for the three months ended September 30, 2012. Professional consulting expenditures were lower in the fourth quarter of fiscal 2013 as compared to the fourth quarter of fiscal 2012 due to professional fees related to corporate finance and audit services incurred in fiscal 2012.

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 \$143,000 for the three months ended September 30, 2013 compared to \$92,000 for the three months ended September 30, 2012. The increase in sales and marketing expenses for the three months ended September 30, 2013 compared to the three months ended September 30, 2012 was primarily a result of increased expenditures on conferences, travelling and marketing consulting fees.

Non-cash stock based compensation charges totalled \$83,000 for the three months ended September 30, 2013 (fiscal 2013 - \$499,000) compared to \$125,000 for the three months ended September 30, 2012 (fiscal 2012 - \$543,000). 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 \$6,000 for the three months ended September 30, 2013 (fiscal 2013 - \$24,000) compared to \$7,000 for three months ended September 30, 2012 (fiscal 2012 - \$11,000). The Company invests its cash in variable term cashable government investment certificates and short-term money market deposits.

## **OUTLOOK AND FUTURE PROSPECTS**

The Company established a large portfolio of potential Diagnostic Tools and Services Customers during fiscal 2013. Business development activities through the year have resulted in launching evaluation projects with very noteworthy leaders in the pharmaceutical industry. Among these, is Bristol Myers Squibb, who presented a very favourable comparison of SQI's custom product's performance at the Bioassay and Bioanalytical Method Development Conference in Berkley California on October 8, 2012. The Company also completed a very successful 21-biomarker custom evaluation project for another, un-named global pharmaceutical company. We believe that both of these evaluations will proceed to the next, expected commercial phase where SQI will produce and sell test kits for either its fully automated sqidlite or semi-automated sqid-X platform. One case could result in the purchase of the custom product for use on an SQI platform in a portion of the customer's human clinical trials and, in the other case, we believe that this customer has initiated the internal processes to acquire a sqidlite platform and will purchase the custom developed kits to process samples generated by their clinical testing studies.

The DTS business is focussed on applying our core IVD technologies, software and platforms to enable pharmaceutical companies and CROs involved in drug development with single test

biomarker panels to move to multiplexed assays on the SQI technology platform. We believe that our products bring significant advantages to these customers that include superior test performance, reduced costs to run the tests and a variety of technical benefits related to multiplexing of antibodies specific to the drugs in development. Management believes that SQI is the only company that can multiplex the antibody response, in single test and, we also provide a fully automated machine to process the high volumes of tests produced during clinical trials.

A presentation and poster presented by Bristol-Myers Squibb at the Bioassays and Bioanalytical Method Development Conference in Berkeley, CA highlighted performance data comparing a custom immunogenicity assay built by SQI for a Bristol-Myers Squibb drug using SQI's Ig\_plex technology. The data compared this assay to a standard ELISA assay as well as another competitive technology demonstrating SQI's superior performance. While technical in nature, the SQI tests were reported to be at least twice as sensitive as current ELISA tests and eight times more sensitive than a commonly used "bridging" test. Further, the SQI test was shown to be much more tolerant to the presence of the drug in the patient, a common issue encountered when using most tests in this field.

We believe that our multiplex automated platforms (sqidworks and sqidlite) and our semi-automated sqid-X, are unique in this market and if provided to customers will enable a broader adoption of multiplexed tests from which we could generate revenue streams including: Diagnostic Tools and Services assay development fees; product revenue from the manufacture of custom and standard biomarker kits; software revenues; and platform revenues from the sale of primarily sqidlite units, but also sqidworks and sqid-X units.

The ideal customer targets are those that have either tried to apply competing bead-based multiplexing technologies or planar microarrays (or both) to antibody-based immunologic tests or panels requiring multiple biomarkers.

Management believes that the successful delivery of the custom Ig\_plex assays to Global Pharma 1 and 2 as well as the new projects with Isis Pharmaceuticals and Global Pharma 3 will result in additional commercial traction with these customers as well as accelerate our efforts to generate sales with additional Diagnostic Tools and Services customers.

Management expects losses to continue for fiscal 2014 as investment continues in product development and commercialization efforts on 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 2014 as it generates revenues and margin from a variety of Diagnostic Tools and Services' customers. Successful clearance of its IVD Celiac test, expected to be completed in fiscal 2014, if completed early enough in the fiscal year, could result in revenue and cash generation in fiscal 2014, further reducing overall losses

Early in fiscal 2013 the Company established a special committee to review strategic alternatives. The Company's advisers generated interest from a number of parties, however no agreements were reached. In light of the recent commercial progress with the Diagnostic Tools and Services offering, the Company decided to place the assessment of strategic alternatives on hold and the special committee has been disbanded.

SQI's operational objectives for 2014 are: generate revenue from custom Ig\_plex products and services from our current proof-of-concept initiatives and contracts with our Global Pharma customer and prospects; continue to establish and grow our custom Ig\_plex sales pipeline based on current successes; continue successful commercialization and continuous improvement of a menu of autoimmune test kits; and, expand partnerships and other strategic relationships to enhance our product offerings and revenues. Success in these steps will allow the Company to further validate its multiplexing model, value proposition and to roll-out and sell its products to customers in its target markets.

## Sources and Uses of Cash

Operational activities for the year ended September 30, 2013 were financed by cash on hand.

At September 30, 2013, current assets were \$1,724,000 compared to \$4,208,000 at September 30, 2012. Working capital as at September 30, 2013 was \$1,270,000 compared to \$3,190,000 at September 30, 2012.

Cash used in investing activities for the year ended September 30, 2013 was \$429,000 compared to \$432,000 for the year ended September 30, 2012. Investing activities focussed on enhancing and maintaining the Company's patent and trademark portfolio and continued development of the sqidlite and sqid-X platforms.

On May 2, 2013 the Company completed a non-brokered private placement of 5,126,044 units of the Company at \$0.75 per unit for gross proceeds of \$3,845,000.

Subsequent to year end 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 million.

## 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 January 27, 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

***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 and \$6.2 million during fiscal 2008, 2009, 2010, 2011 2012 and 2013, respectively. As of September 30, 2013, we had an accumulated deficit of \$56.9 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.

***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 3 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.

***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 assays 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 assays to potential customers. To date, we have obtained regulatory approval for only a few diagnostic assays.

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 assays. 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 assays 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 January 27, 2014, there were 47,936,058 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 January 27, 2014:

<b>Number of Warrants</b>	<b>Purchase Price</b>	<b>Weighted average time to maturity</b>
1,140	\$5.00	1.87 years
1,199	\$4.00	0.18 years
5,784	\$2.50	0.41 years
210	\$1.75	0.63 years
5,126	\$1.10	1.58 years
513	\$0.75	1.58 years
2,965	\$0.65	2 years
297	\$0.50	2 years
<b>17,234</b>		

The Company had the following stock options outstanding under the Plan at January 27, 2014:

<b>Number of Options</b>	<b>Range of Exercise Prices</b>	<b>Weighted average time to maturity</b>
1,404	\$0.35 - 1.31	3.83 years
655	\$1.32 - 2.28	2.65 years
327	\$2.29 - 3.26	1.57 years
<b>2,386</b>		

### Off-Balance Sheet Arrangements

The Company has no off-balance sheet arrangements.

## **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, 2013;
- (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, 2013; 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.