

# **SQI Diagnostics Inc.**

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

**September 30, 2011**

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

*This discussion and analysis covers the unaudited financial statements for the years ended September 30, 2011 and 2010, prepared in accordance with Canadian generally accepted accounting principles (Canadian GAAP). The fiscal year end of SQI Diagnostics Inc. ("SQI" or "Company") is September 30<sup>th</sup>.*

*All amounts are expressed in Canadian dollars unless otherwise indicated.*

*This discussion and analysis was prepared by management using information available as at December 20, 2011.*

*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 and 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 systems;*
- our plans to retain and recruit personnel;*
- our ability to satisfy customer demand for our systems;*
- our plans to correct defects or errors in our systems;*
- the effect of litigation on our business;*
- our strategy with respect to the protection of our intellectual property; and*
- our expectations with respect to existing and future corporate alliances and licensing transactions with third parties, and the receipt and timing of any payments to be made by us or to us in respect of such arrangements.*

*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 reliance on a few key and significant customers;*
- *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;*
- *the impact of liability from the use of hazardous and biological materials and other claims;*
- *our ability to successfully manage fluctuations in revenue;*
- *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;*
- *changing market conditions;*
- *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 a life sciences Company that develops and commercializes proprietary technologies and products for advanced microarray diagnostics. Our goal is to become a leader in the development and commercialization of microarray and multiplexed diagnostics by offering our customers a comprehensive “turnkey” solution that increases the efficiency and ease of diagnostic testing and test development.

Our target customers – clinical, academic and diagnostic development laboratories – require diagnostic processing equipment and consumable tests (“systems”) that are capable of processing large numbers of patient samples at low cost and with minimal labour requirements (“high-throughput systems”). High-throughput systems have not been widely employed in autoimmune disease, allergen or companion diagnostics testing and only limited use of high-throughput systems exists in infectious disease testing. To our knowledge, no fully-automated high-throughput systems exist that are capable of addressing the combined multiplex testing needs of these markets. A fully-automated system capable of providing multiple biomarker measurements in a single test array has the potential to increase a laboratory’s throughput with significantly less labour, consumables and other costs

Our proprietary microarray tests and automated systems are designed to simplify antigen, protein and antibody testing workflow, increase throughput, reduce costs and provide excellent

data quality. In many instances, our technology enables analysis that was traditionally unavailable.

Our high-throughput SQiDworks diagnostic platform is a fully-automated microarray processing and analytical instrument, which provides significant cost savings and other benefits over existing technologies. Additionally, the incremental cost savings of tests run on our fully-automated platform versus existing technologies increase as the complexity of the test increases.

Our IgX PLEX microarrays have the ability to accurately measure multiple biomarkers in a single test. Additionally, our microarray technology uses less patient blood and has fewer steps than traditional methods, which increases the predictive value of the test. The increased predictive value of the test may allow the healthcare provider to choose a treatment plan earlier in the course of the disease.

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 using their own biomarkers.

The Company has been primarily involved in research, development and commercialization activities related to its core technology platform since 2003. The Company has expended significant resources to create and protect its technology platform through the filing of patents and in building an automated instrument and multiplexed assay platform. The Company has invested in fostering partnerships with clinicians who are leaders in our disease areas of focus and with potential novel biomarker collaborators. The Company has also incurred costs associated with gathering market intelligence concerning prospective customers, developing a direct sales platform and in marketing and selling to prospective customers.

The Company has developed its fully automated SQiDworks and SQiDLITE and semi-automated SQiDman™ microarray-based test platforms that enable laboratory customers to generate multiple patient test results with less than one unit of traditional 'test effort'. The Company has received marketing clearance from the United States Food & Drug Administration ("FDA"), Canadian regulatory approval for, and has CE Marked, its fully automated, high throughput SQiDworks platform. SQiDworks is the only fully-automated microarray processing system to achieve these regulatory clearances.

The SQiD platforms are to be used to run a menu of tests used to aid in the diagnosis of a wide range of diseases in targeted market segments. The Company has received clearance from the FDA and Canadian regulatory approval for qualitative rheumatoid arthritis (RA) test kits used to detect and measure a panel of biomarkers to aid in the diagnosis of rheumatoid arthritis. The Company has also received clearance from the FDA and Canadian regulatory approval for qualitative celiac disease test kits run on the SQiDworks platform. The quantitative RA assay has been licensed in Canada and CE Marked in Europe. The quantitative celiac assay has been licensed in Canada and CE Marked in Europe.

The Company is focusing on the continued development of a pipeline of other tests that can be processed on the SQiDworks platform. The Company is moving these assays through the development pipeline and expects to advance additional test kits through the regulatory process during fiscal 2012 as discussed further in this document. The Company is also focused on the release of SQiDLITE, our second generation diagnostic platform. This platform is a fully-automated microarray processing and analytic platform. 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. This system is based on the same technology and uses many of the same components as our SQiDworks system. It is targeted at small to medium sized clinical and diagnostic customers. During the year the Company previewed a prototype of the SQiDLITE system at the American Association for Clinical Chemistry Annual Conference (24-28 July 2011).

In the second half of fiscal 2011 we added additional products and services targeted at laboratory and other diagnostic customers to leverage our expertise in assay design and microarray printing. This Diagnostic Tools and Services offerings will enable customers to build panels of existing single biomarker tests into microarrays that they can then offer to their customers. These multiplexed test panels may then be sold and used as either Research Use Only (RUO) or Lab Developed Tests (LDT). The Diagnostic Tools and Services is intended to bring product and service-based revenue to SQI sooner in the product development cycle, reduce our development risk by utilizing the customer's existing content, and reduce regulatory risks by either the selective targeting of RUO and LDT prospects, or by transferring products to these customers prior to validation and regulatory processes.

### Status of Development Program

The Company's development program includes several major components which the Company expects will advance its commercialization strategy. As a result of a business realignment that was announced on November 30, 2011 the Company has streamlined its IVD product development pipeline. The impact of this realignment was to focus more intensively on completing products in final development and to shift all products in development such that fewer products would be in active development at any given time. The status of each component is summarized and discussed in further detail below:

Product	Development Status	Approval Status		
		Canada	United States	Europe
SQiDworks™ Diagnostics Platform	Complete	Licensed	Cleared as a system with IgX PLEX RA Assay	CE Marked
SQiDLITE Platform	Development			
SQiDman Analyzer	Development - RUO	Not required - RUO	Not required - RUO	Not required - RUO
IgX PLEX Rheumatoid Arthritis Assay (Qualitative)	Complete	Licensed	Cleared	
IgX PLEX Rheumatoid Arthritis Assay (Quantitative) *	Complete	Licensed		CE Marked
IgX PLEX Celiac (Qualitative)	Complete	Licensed	Cleared	

Product	Development Status	Approval Status		
		Canada	United States	Europe
IgX PLEX Celiac Panel (Quantitative)	Complete	Licensed		CE Marked
IgX PLEX Celiac DGP Panel (Quantitative)	Final Development - Active			
IgX PLEX Vasculitis Panel (Quantitative)	Final Development - Active			
IgX PLEX Rheumatoid Arthritis Panel with expanded markers (Quantitative)	Final Development - on hold			
IgX PLEX Lupus Panel (Quantitative)	Development - on hold			
IgX PLEX TNF Assay (Quantitative)	Development - on hold			
IgX PLEX IBD - Crohn's Disease (Quantitative)	Proof of Concept - on hold			
IgX PLEX APS (Quantitative)	Proof of Concept - on hold			

\* Marketed in Canada under the name "QuantiSpot Rheumatoid Arthritis"

The Company's SQiDworks and SQiDman platforms are also capable of running RUO and Investigational Use Only (IUO) test kits and the Company is exploring sales opportunities related to these applications of its platform with the Company's products as well as through the potential development of target customers' content. Delivering RUO/IUO product based on customer owned content would require collaboration and assay development though this effort would be materially less than that experienced with the Company's pipeline of regulatory-cleared products. Management believes this creates additional new revenue opportunities for the Company.

Platform development of SQiDLITE was continued throughout the final two quarters of 2011 with a target to complete development on a timeline to coincide with customer requirements for early in calendar 2012. The development of the SQiDLITE platform addresses the needs of smaller and mid-market IVD customers, of prospects in the Diagnostic Tools and Services market, and of the research market.

The Company continues to focus on its in-market IVD tests and believes that it must continuously improve and update its products. The Company has identified and has moved into development enhancements to the existing RA and celiac test panels (see status of Commercialization Activities below). These enhancements include fully quantitative IgX PLEX microarray technology and expanded biomarker content. The Health Canada approval for IgX PLEX Celiac Quantitative test kit represents the first approval of the Company's second generation fully quantitative test. All in-development tests will utilize this second generation, fully quantitative multiplexing technology; the Company believes these enhancements will provide significant market advantages compared to our competitors.

### **Status of Commercialization Activities and Other Events in the Fiscal Year**

During the year ended September 30, 2011, the Company invested in its sales and marketing team, its science, commercialization, and regulatory groups, and in infrastructure. The Company's sales efforts are focusing on the North American market and European targets to generate sales to targeted customers of the currently approved system, including the SQiDworks fully automated analytical platform and RA and celiac tests. The Company has also focussed its sales and business development efforts on the Diagnostic Tools and Services opportunities to provide a range of products and services to other diagnostic companies and diagnostic laboratories.

Following is an overview of the Company's achievements for the fiscal year:

- (a) The Company continued to develop its commercial relationship with Gamma Dynacare Medical Labs (GDML). The Company is working closely with GDML to develop its multiplexed RA business and in January 2011 GDML released its newsletter that focused on our RA multiplexed product. This marketing material described the benefits of multiplexing rheumatoid arthritis biomarkers on an automated platform to all of GDML's customers and is featured on GDML's website. The Company believes that this and similar marketing efforts will drive the continued growth of our RA product at GDML.
- (b) The Company has provided quantitative celiac test kits on an investigational use only basis to GDML enabling their internal review of the product's performance. The internal review by GDML, completed in 2011, is expected to lead to the expansion of the current contract to include the sale to them of our quantitative celiac test kits.
- (c) Progressed a number of pipeline diagnostic tests through our discovery and development program;
  - (i) the Company received FDA clearance for its automated SQiDworks diagnostics platform and its IgX PLEX celiac qualitative assay for marketing in the United States and Health Canada approval for our quantitative celiac test.
  - (ii) The Company's vasculitis assay continues to progress through the assay development pipeline. Collaborative studies demonstrating the utility of the Company's assays were presented at the 15<sup>th</sup> International Vasculitis and ANCA Workshop May 15<sup>th</sup> - 18<sup>th</sup>, 2011.
  - (iii) The Company's quantitative lupus test panel is being held, in the assay development stage. Moving the lupus panel through development is a significant achievement.

The current development results show that SQI is able to effectively multiplex up to 15 protein biomarkers, including double stranded DNA in a single microarray. This is our largest panel to date and management believes that, if successfully completed and approved, it will provide SQI with the only such product in the market. Management also believes that the successful completion and clearance of the lupus product will be transformative to the Company's commercial position. The Company expects to initiate clinical validation of this product in the second half of calendar 2012, and to complete regulatory filings shortly thereafter.

- (iv) The Company's IBD-Crohn's candidate test panel is in the proof-of-concept stage and while currently on-hold, is being targeted to go into active development during calendar 2012.
- (d) The Company completed the prototype of its SQiDLITE platform and showcased the system to target Diagnostic Tools and Services customers at AACC in July, 2011. Commercial completion of this platform is expected to occur to address specific customer demands in early calendar 2012.
- (e) Diagnostic Tools and Services software (*Automated Assay Development Toolkit*) was completed, subsequent to the period end. This product is intended to be sold to assist DTS customers to work with SQI assay development teams in the product development process or to be used by RUO and LDT customers to use the many features of the SQiDworks and SQiDLITE platforms to optimize the performance of multiplexed tests.
- (f) Partnering Summary

The following table provides an overview of our partnering collaborations and the relevant pipeline product as at the period end:

Partner Institute	Pipeline Product	Purpose
Cleveland Clinic	Rheumatoid arthritis, IBD	Serum Samples Clinical Validation Collaboration
Beth Israel Deaconess Medical Center	Celiac, anti-TNF	Serum Samples Collaboration / Publication
Hospital Clinic De Barcelona, Spain	Vasculitis	Serum Samples Collaboration / Publication
University Hospital Maastricht, The Netherlands	Vasculitis	Serum Samples Collaboration
The University of North Carolina at Chapel Hill	Vasculitis	Collaboration Serum Samples Clinical Validation

\*All Partnering Institutes are located in the USA unless otherwise annotated.

## CORPORATE FINANCING TRANSACTIONS

During the year ended September 30, 2011 a total of 81,668 employee stock options were exercised at an average price of \$1.45 for total proceeds of \$119,000.

During the fiscal year 106,520 warrants with an expiry of January 22, 2011 were exercised resulting in the issuance of 106,520 shares for total proceeds of \$133,000. In addition, 143,886 warrants with an expiry of December 4, 2010 expired unexercised.

On October 5, 2011 the Company announced that it would not proceed with its previously announced financing and withdrew its preliminary short form base PREP prospectus with the Ontario Securities Commission and withdrew the corresponding registration statement on Form F-10 filed with the Securities and Exchange Commission. Costs relating to the financing were \$956,000. These costs have been expensed in the current year as they no longer meet the criteria for deferral.

Owing to the withdrawal of the prospectus and registration statement and the termination of the financing, effective October 6 2011, closing conditions to the Company's acquisition of Scienion AG were not met, and the Company therefore did not complete the acquisition as contemplated. Costs of \$697,000 relating to the acquisition have been expensed in the current year.

On October 26, 2011 the Company announced that it had raised \$4,552,000 through a non-brokered private placement of 2,276,000 units of the Company at a price of \$2.00 per unit.

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 \$2.50 for a period of two years from the date of issuance, provided that if on any day that is 12 months following the date of issuance the 20-day volume weighted average trading price of the Company's shares on the TSX Venture Exchange equals or exceeds \$3.25, then upon the Company sending subscribers written notice of such date and issuing a news release announcing such date, the common share purchase warrants will only be exercisable for a period of 30 days following the date on which such written notice is sent to the subscribers.

In connection with the private placement, the Company paid a finder's fee equal to 6% of the gross proceeds and issued 85,040 compensation warrants exercisable for 24 months from the closing of the Private Placement. Each warrant is exercisable into one common share and one warrant at a price of \$2.00. Each underlying warrant is exercisable into one common share at a price of \$2.50 for a two year period

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

These financial statements are prepared in accordance with Canadian GAAP. The significant accounting policies that management believes are the most critical in fully understanding and evaluating the reported financial results include the following:

### **Patents and Trademarks**

The costs relating to patent and trademark fees are deferred and amortized over 10 years on a straight-line basis.

### **Research and Development Costs**

Research costs are charged to earnings in the period in which they are incurred. Development costs are expensed as incurred or deferred if they meet the criteria for deferral under Canadian generally accepted accounting principles and are expected to provide future benefits with reasonable certainty. At September 30, 2011, the Company has developed a pipeline of novel tests for its diagnostic system. Deferral criteria have not yet been met, and accordingly, all development costs have been expensed.

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

The Company applies a fair value based method of accounting for all stock-based payments. Accordingly, stock-based payments are measured at the fair value of the consideration received or the fair value of the equity instruments issued or liabilities incurred, whichever is more reliably measurable. Stock-based compensation is charged to operations over the vesting period and the offset is credited to contributed surplus. Consideration received upon the exercise of stock options is credited to share capital, at which time, the related contributed surplus is transferred to share capital.

### **Share Issuance Costs**

Costs incurred in connection with the issuance of capital stock are netted against the proceeds received.

### **Income Taxes**

The Company follows the liability method of accounting for income taxes. Under this method, future 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. Future 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. Future income tax assets are recorded in the financial statements if realization is considered more likely than not.

### **Use of Estimates**

The preparation of financial statements in conformity with Canadian generally accepted accounting principles 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 year. 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, valuation of investment tax credits receivable, valuation of stock options and warrants and valuation allowance on future tax assets.

## Recent Accounting Pronouncements

### (i) Adoption of New Accounting Pronouncements Business Combinations

In January 2009, the CICA issued Section 1582, Business Combinations, which replaces former guidance on business combinations. Section 1582 establishes principles and requirements of the acquisition method for business combinations and related disclosures. In addition, the CICA issued Sections 1601, Consolidated Financial Statements, and 1602, Non-Controlling Interests, which replaces the existing guidance. Section 1601 establishes standards for the preparation of consolidated financial statements, while section 1602 provides guidance on accounting for a non-controlling interest in a subsidiary in consolidated financial statements subsequent to a business combination.

These standards apply prospectively to business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after January 1, 2011 with earlier application permitted. The Company adopted the new standards on October 1, 2010.

### (ii) Recent Accounting Pronouncements Issued and Not Yet Applied International Financial Reporting Standards (IFRS)

Effective January 1, 2011 the CICA has adopted International Financial Reporting Standards ("IFRS"). The Company will be required to adopt IFRS for its 2012 fiscal year and will be required to provide IFRS comparative information for the previous fiscal year. The Company continues to assess and plan for the conversion to IFRS. We have identified the main differences between existing Canadian GAAP and IFRS standards and begun quantifying the reporting differences. The Company has a conversion plan in place and believes it has the resources in place to meet the conversion timelines. The following are the main differences and the expected impact on our business processes and information systems:

Key Accounting Areas	Expected impact on the Company
IFRS 1 First time adoption of IFRS	The Company has selected the applicable exemptions under IFRS. Additional reconciliations and disclosure upon the initial conversion to IFRS will be included in the initial statements presented under IFRS commencing in the first quarter of fiscal 2012. The Company has begun the process of assessing and preparing the additional reconciliations. The Company is reviewing the disclosure requirements including the disclosure of other corporations which have already adopted IFRS.
IAS 16 Property Plant and Equipment	The Company is finalizing a study of the useful life of each component of property plant and equipment and will restate, if applicable, the historic amortization expense. Based on our analysis the Company does not expect a material adjustment upon adoption of IFRS.
IAS 36 Impairment of Assets	The Company will evaluate potential impairments using discounted cash flow analysis as required under IFRS. Based on our analysis the Company does not expect a material adjustment upon adoption of IFRS.

IAS 12 Income Tax	The Company has accumulated non-capital losses, undeducted scientific research and development costs, and investment tax credits that have not been reflected in the financial statements. These items will need to be assessed based on the IFRS criteria to ensure proper classification on the balance sheet. The Company believes that these items will not meet the criteria for inclusion on the balance sheet and will continue to be disclosed in the notes to the annual financial statements.
IFRS 2 Share based payments	IFRS 2 requires that each tranche of options with graded vesting be treated as a separate award. IFRS 2 also requires an estimate of forfeitures to be factored into the determination of compensations costs. The Company expects to utilize the exemptions under IFRS 1 when converting to the new standard. The Company has begun to calculate the impact on all unvested tranches of options at the date of transition. Based on our preliminary calculation we expect the adjustment to increase the opening deficit by \$180,000.
IAS 1 Financial Statement Presentation	Additional disclosure required as well as selection between presentation alternative will be addressed in the initial statements presented under IFRS. The Company is analyzing the impact of the changes on its financial statements through a review of the standards as well as a review of the financial reports of corporations with earlier adoption dates. The Company does not believe there will be a material change to its financial statement presentation.

The Company believes it has the financial reporting expertise in place to complete the transition to IFRS and does not believe the transition will materially impact its business activities. As the review of accounting policies is finalized, we will review internal controls over financial reporting and the disclosure controls and policies and, where necessary, changes will be made.

The Company believes the only area of impact to result from IFRS 2 Share based payments. The implementation of the changes as a result of adopting IFRS 2 is not expected to have a material impact on the Company's internal controls over financial reporting or its disclosure controls and policies.

## SELECTED FINANCIAL INFORMATION

The table below summarizes annual financial information for the fiscal years ending September 30, 2011 and 2010.

	Year ending September 30, 2011 (000s)	Year ending September 30, 2010 (000s)
<b>Revenue</b>	\$ 36	\$ 35
<b>Net loss</b>	\$ 10,747	\$ 8,073
<b>Net loss per share</b>	\$ (0.32)	\$ (0.27)
<b>Weighted average shares</b>	33,874	30,349
<b>Total Assets</b>	4,734	13,134

The increase in net loss for the year ended September 30, 2011 as compared to the loss for the year ended September 30, 2010 was primarily related to increase development activity and costs for the scientific discovery and development of several IgX PLEX assays (see status of development table).

The increase in the net loss for 2011 versus 2010 is also attributable to a onetime charge relating to the write-off of lab equipment, increased professional fees relating to the proposed acquisition of Scienion and the proposed financing, as well as increased personnel, salaries and occupancy costs.

Revenue for the year ended September 30, 2011 was \$36,000 versus \$35,000 for the year ended September 30, 2010. Revenues in the 2011 fiscal year were primarily from sales of our QuantiSpot RA test kit whereas revenues for the 2010 fiscal year were primarily a result of consulting services provided to a related party.

Gross research and development (R&D) costs, which include R&D salaries, laboratory consumables and operating expenses, clinical studies, scientific consultants and clinical partner costs were \$5,756,000 for the year ending September 30, 2011 compared to \$5,354,000 for the year ending September 30, 2010. The increase in R&D expenditures of \$411,000 is a result of increased personnel costs.

In fiscal 2010 the Company expanded its number of R&D employees to a peak of 44 which represented an increase of 15 employees. This peak occurred in the final half of the fiscal year. Headcount levels remained unchanged from this point through to the end of fiscal 2011. R&D salaries and payroll costs increased from \$3,159,000 for the year ended September 30, 2010 to \$3,604,000 for the year ended September 30, 2011. The difference between the two periods

resulted from the annualized effects of the personnel increases over the 2010 fiscal year being applied to the entire year in 2011.

Gross R&D expenses were offset by the recognition of Scientific Research and Experimental Development (SRED) cash refunds received in the 2010 fiscal year of \$295,000 resulting in net R&D expense of \$5,059,000 and by \$300,000 in the fiscal 2011 period resulting in net R&D expense of \$5,456,000.

Professional and consulting fees increased from \$659,000 in the year ended September 30, 2010 to \$2,083,000 in the year ended September 30, 2011. The increase is due to \$956,000 of costs retaining to the proposed financing and \$697,000 of costs relating to the proposed acquisition that were expensed in the current year. These costs were offset by a decline in recruiting fees in fiscal 2011 versus fiscal 2010.

Salary and wages include, primarily, all 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 increased by \$260,000 in fiscal 2011 due to a combination of increased salaries and increased personnel.

General and administrative (G&A) expenses include occupancy costs (rent, maintenance and utilities), office supplies as well as other general operating costs and bank charges. G&A expenses increased in the year ending September 30, 2011 compared to the period ending September 30, 2010 from \$471,000 to \$737,000. The increase of \$266,000 is due to increased travel and filing fees related to the acquisition and financing, increased rent expense, and a loss incurred on the sale of equipment.

## Fourth Quarter Commentary

The table below summarizes quarterly financial information for the 3 month periods shown.

	September 30, 2011 (000s)	June 30, 2011 (000s)	March 31, 2011 (000s)	December 31, 2010 (000s)
Revenue	\$ 5	\$ 9	\$ 4	\$ 18
Net Loss	\$ 3,927	\$ 2,691	\$ 1,874	\$ 2,255
Net Loss Per Share	\$ (0.12)	\$ (0.08)	\$ (0.06)	\$ (0.07)
Weighted Average Shares	33,946	33,936	33,852	33,759

	September 30, 2010 (000s)	June 30, 2010 (000s)	March 31, 2010 (000s)	December 31, 2009 (000s)
Revenue	\$ 14	\$ 6	\$ 10	\$ 5
Net Loss	\$ 2,621	\$ 1,812	\$ 2,020	\$ 1,620
Net Loss Per Share	\$ (0.08)	\$ (0.06)	\$ (0.07)	\$ (0.06)
Weighted Average Shares	32,705	30,790	29,917	27,930

Revenue for the quarter-ended September 30, 2011 was \$5,000 compared to \$14,000 for the quarter-ended September 30, 2010. Revenue for the three months ended September 30, 2011 included sales of its QuantiSpot RA test kits. Revenue in the three months ended September 30, 2010 resulted from sales of QuantiSpot RA test kits and consulting services provided to a related party. The reduction in revenue was owing to the complete reduction in laboratory services provided to a related party in 2010 but that was discontinued in 2011. The discontinued revenue was not related to any of the Company's diagnostic customers, products or services revenues.

For the quarter-ended September 30, 2011, the Company recorded a net loss of \$3,927,000 (\$0.12 net loss per share) compared to a net loss of \$2,621,000 (\$0.08 net loss per share) for the quarter-ended September 30, 2010. Per share values are based on the weighted average shares outstanding in the period. For the quarter-ended September 30, 2011 there was an average of 33,946,000 shares outstanding.

The net loss was greater for the three months ended September 30, 2011 compared to the three months ended September 30, 2010. The Company incurred significant costs in the last quarter of 2011 relating to the proposed financing, registration and initial public offering in the US, and the proposed acquisition of Scienion. In addition, the Company incurred a one-time charge of \$251,000 relating to the write off of laboratory equipment. This equipment will not be used in research and development activities for assays and will no longer be incorporated into future SQiDworks platforms. A replacement component with enhanced capabilities was tested and incorporated into the updated SQiDworks and SQiDLITE platforms and is being used in development testing.

R&D expenditures for the fourth quarter-ended September 30, 2011 were \$1,400,000 compared to the \$1,621,000 for the fourth quarter-ended September 30, 2010. The decrease in R&D expense

resulted from the reduced expenditures on lab consumables, scientific consultants and partnering and validation costs. The overall decrease reflects the reduced validation costs incurred in the current quarter versus significant validation costs in the fourth quarter of 2010, and the Company's focus on accelerating the celiac quantitative assay through the regulatory approval process and reducing efforts on assays that were earlier in the development cycle in an effort to conserve cash balances.

Corporate expenses include, primarily, 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. General and Administrative expenses include facility costs, insurance costs, and foreign exchange expenses. Corporate and general expenses totalled \$497,000 for the three months ended September 30, 2011 compared to \$299,000 for the three months ended September 30, 2010. The increase from the three months ended September 30, 2011 compared to the same periods in 2010 was primarily a result of higher salary costs, increased personnel and increased occupancy costs. Also included in corporate and general expense for the year ended September 30, 2011 are travel costs and other filing costs related to the terminated financing and a loss on the sale of equipment.

Professional consulting (legal, accounting, Board of Directors compensation, recruiting, administrative contractor, and investor relations) costs in the three months ended September 30, 2011 were \$1,414,000 compared to \$222,000 for the three months ended September 30, 2010. The increase in professional and consulting costs in the three months ended September 30, 2011 was primarily related to legal and consulting costs related to the acquisition of Scienion as well as professional costs relating to the terminated financing.

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 totalled \$119,000 for the three months ended September 30, 2011 compared to \$165,000 for the three months ended September 30, 2010. The decrease in sales and marketing expenses for the year ended September 30, 2011 compared to the year ended September 30, 2010 were primarily related to sales incentives paid in fiscal 2010 upon the placement of the first platform and sale of product with a customer.

Operational expenses were partially offset by interest income earned on short-term investments of \$5,000 for the three months ended September 30, 2011 (fiscal 2011 - \$61,000) compared to \$12,000 for three months ended September 30, 2010 (fiscal 2010 - \$32,000). The Company invests its cash in variable term cashable government investment certificates and short-term money market deposits.

Non-cash stock based compensation charges totalled \$103,000 for the three months ended September 30, 2011 (fiscal 2011 - \$475,000) compared to \$290,000 for the three months ended September 30, 2010 (fiscal 2010 - \$402,000). The related stock option issuances are described further below in the Outstanding Share Capital section.

## OUTLOOK

The Company's announced business realignment on November 30, 2011 streamlined its IVD product development pipeline. This realignment will focus the Company's R&D efforts more intensively on completing products currently in final development. Products in other stages of development will be held pending successful completion of late stage assays and then will be moved, one at a time, into active development. The Company believes this staging of assays in development will enhance the progression of assays being filed for regulatory review. The Company will also focus on converting several of the many current prospects for our Diagnostic Tools and Services offerings in order to generate near term revenues.

The Company launched its Diagnostics Tools and Services business line in the second half of 2011. This business is focussed on using our core IVD development technologies, software and platforms to enable other diagnostic customers and laboratories with their single test biomarker panels to move to multiplexed assays on the SQI technology platform. We believe that our unique technology is attractive to prospects who desire multiplexed assays but do not have the capability to commercialize multiplexed tests. We also believe that our multiplex automated platforms (SQiDworks, SQiDLITE, SQiDman) are unique in this market and if provided to customers on an OEM basis will enable a broader adoption of multiplexed tests that we could generate revenue streams from across lines: Diagnostic Tools and Services assay development fees; product revenue from the manufacture of OEM kits; software revenues; platform revenues from the sale of primarily SQiDLITE units, but also SQiDworks and SQiDman units. Management believes that the success of these potential diagnostic customers may cause the proliferation of SQiD-platforms in the market and a greater potential installed base of platforms that could be used to run a variety of IgX PLEX test kits, including our own IVD and RUO kits.

Management expects losses to continue for the fiscal 2012 year as investment continues in product development and commercialization efforts on its pipeline of autoimmune test kits and platforms, as well as investment in sales and marketing. During the 2012 fiscal year the Company will continue to leverage its growing autoimmune test menu and focus on sales and placing SQiDworks systems in Canadian, US and European customers for system evaluation. We expect that some, or all, of these evaluation placements will lead to commercial acceptance and revenues from sales of consumable test kits in the future. The Company's customer, GDML is presently evaluating the quantitative celiac test kits and management is optimistic that this evaluation will lead to additional revenues from GDML attributed to IgX PLEX Quantitative Celiac kits in fiscal 2012.

### **The Market for Our Products**

The diagnostic products and services market is increasing in importance, complexity, breadth and size. Diagnostics are critical to high-quality healthcare and guide a majority of clinical decisions.

Researchers and laboratories are accelerating the rate at which new biomarkers are being commercialized for the known set of diseases being diagnosed today. It is estimated that an additional 30,000 biomarkers (molecular and protein) in various stages of development have been identified and not yet commercialized. We believe that the increased use of existing assays and the introduction of new assays will drive growth of the diagnostics testing market, a market that is estimated to have a growth rate of approximately five to nine percent annually from 2009 to 2014.

Our strategy is to focus initially on the immunoassay segment of the diagnostic test market since there are no multiplexed, microarray, IVD solutions in the immunoassay space. The 2012 global immunoassay diagnostic test market is estimated to be US\$10.3 billion, of which approximately US\$4.5 billion is within our strategic market focus, which includes tests for autoimmune disease, infectious disease, and allergen tests. These three markets are estimated to be US\$1.5 billion, US\$2.4 billion and US\$0.6 billion, respectively.

### **Autoimmune Disease Tests**

Our primary testing market in the immunoassay segment is for products that aid in the diagnosis of autoimmune disease, which is estimated to be approximately US\$1.5 billion per year.

Management believes the number of potential customers will, upon regulatory clearance of multiple products (ex RA and celiac) in the US, greatly exceed the number of customers currently targeted with only two approved product in the US. Following licensing in Canada of its second generation fully quantitative celiac product the Company has intensified its Canadian sales efforts and is optimistic that it will convert additional Canadian reference laboratories to customers in the ensuing several quarters. Subsequent to the year ending September 30, 2011, the Company began exploring customer opportunities in a focused business development effort in Europe based on selling its two CE marked quantitative products. The initial feedback on the benefits and performance of the SQiDworks platform and multiplexed test panels for RA and celiac testing has been very positive. These meetings have also resulted in a positive response to the expanded product and service offerings to assist these customers to convert their content into SQI-based microarrays using the Company's Diagnostic Tools and Services offerings. During the last fiscal quarter of 2011 and first quarter of 2012, the Company continued to evaluate its capability to generate revenue in Europe – successful test marketing may lead the Company to officially launch its European sales efforts in the 2012 calendar year.

### **Infectious Disease and Allergen Tests**

The Company also plans to enter the immunoassay segment of the infectious disease diagnostics market, which is estimated to be approximately US\$2.4 billion for 2012, followed by the immunoassay segment of the allergen diagnostics market, which is approximately US\$0.6 billion for 2012.

### **RUO and Lab-Developed Tests**

An additional market representing approximately 34% of the US\$3.7 billion U.S. annual market for RUO and lab-developed tests is directly addressable by the Company's proprietary technologies. Additionally, we believe that the US\$2.2 billion European market for RUO and lab-developed tests has approximately the same segmentation as the U.S. market. As such, we anticipate the combined U.S. and European markets for RUO and lab-developed tests that are directly addressable by our proprietary technologies to be approximately US\$2 billion.

### **Companion Diagnostics**

The Company believes that the commercialization of "companion diagnostics" tests is a meaningful market opportunity. Autoimmune diseases are increasingly being treated with antibody-based or other biologic drugs. Often, there are different variants of the antibody or biologic drugs. For example, anti-TNF-based drugs are used to treat rheumatoid arthritis, Crohn's disease and IBD. The market for anti-TNF drugs was estimated to be approximately US\$16 billion per year in 2008. Anti-TNF drugs are currently marketed under brand names such

as Remicade®, Enbrel® and Humira® which represented more than 99% of the anti-TNF drug market in 2008. The effectiveness of the treatment of autoimmune patients with these drugs may be enhanced by the monitoring of the concentration of these drugs in a patient's blood by a "companion diagnostic" test. Our multiplexing technology allows us to combine the tests for both the diagnosis and therapeutic monitoring of a patient's disease. We expect this test combination to result in significantly less labour, consumables and other costs and provide us with a large market opportunity.

### **Diagnostic Tools and Services**

During the 2012 calendar year the Company believes it to be strategic to expand its marketing and sales program to RUO/IUO customers that conduct research in the relevant disease markets or to those that have an interest in companion testing during drug development and that are targeted in our clinical areas of interest. The Company may target customers conducting research with its SQiDman platform and RUO/IUO products, higher throughput customers with our SQiDworks platform or SQiDLITE platform. Management believes that SQiDLITE will be an important system for future clinical areas and non-reference lab customers. SQiDLITE is expected to be fully automated, allow smaller batch sizes and to have equivalent analytical performance when compared to the fully automated SQiDworks platform.

We also intend to work with third parties who have developed their own proprietary assay biomarkers for multiplexed tests. Our goal is to provide both these companies and their customers with the services to develop SQI-based microarray tests and with SQiDworks or SQiDLITE systems to process these tests as well as print and manufacturing services for their SQI-based microarray products.

These third parties may include reference laboratories, diagnostic companies, or research organizations. We intend to target companies which have indicated an intention to convert their biomarkers to microarrays but which have been unable to develop fully functioning assay systems or who have customers who require high throughput automated systems to process microarray tests. We believe that our expertise in the areas of microarray printing, microarray test development and systems integration will enable us to generate revenues from customers in a market that is not currently served by a fully integrated service and product offering.

It will also be necessary to invest in expanding the Company's customer service and administrative elements to support our customers and sales, as we become successful in growing our placement of SQiDworks platforms across Canada and the United States, and to increase our product menu available to our customers. Management will add these resources as needed to support forecasted customer installations of SQiDworks platforms and sales of consumable kits.

Management will continue to monitor its cash resources in relation to the capital available to it and will manage cash flows as required in the context of the capital markets. On November 30, 2011, the Company announced a Business Realignment and workforce reduction. The purpose of this realignment was primarily to reduce our cash burn. To continue to achieve material milestones, the Company intends to focus its resources on a reduced number of simultaneous product development programs and intends to place an emphasis on generating Diagnostic Tools and Services revenues from target customers that would provide near-term revenues. Subsequent to the fiscal year ended September 30, 2011, the Company has completed multiple advanced business development meetings and has submitted proposals intended to generate Diagnostic Tools and Services revenues in calendar 2012.

## **Related Party Transactions**

Transactions with related parties occur in the normal course of business and are measured at the exchange amount. Related party transactions are described below, unless they have been disclosed elsewhere in the financial statements.

Included in general and administrative expense for the year ended September 30, 2011 is \$38,000 (2010 - \$49,000) related to recovery of occupancy costs from a corporation in which an officer of the Company is also an officer. Consulting fee revenue of \$9,000 for the year ended September 30, 2011 (2010 - \$30,000) was earned from this corporation. At year-end, NIL (2010 - \$1,000) due from this corporation is included in amounts receivable.

## **Sources and Uses of Cash**

Operational activities for the year ended September 30, 2011 were financed by cash on hand.

At September 30, 2011, current assets were \$1,266,000 compared to \$9,902,000 at September 30, 2010. Working capital as at June 30, 2011 was (\$1,322,000) compared to \$8,930,000 at September 30, 2010.

Cash used in investing activities for the year ended September 30, 2011 was \$748,000 compared to \$593,000 for the year ended September 30, 2010. Increased investing activities during the year was a result of the Company's investments in (1) an overhaul of its out-dated network and data storage infrastructure to expand its data storage capacity required to support the research and development program and to enhance its disaster recovery systems to protect the vast amount of data generated through product development and validation, and (2) a SQiDworks platform for internal use for platform development activities.

During the year ended September 30, 2011 a total of 81,668 options were exercised at an average price of \$1.45 for total proceeds of \$119,000.

During year ended September 30, 2011 106,520 warrants with an expiry date of January 22, 2011 were exercised for total proceeds of \$133,000.

Subsequent to year end the Company raised \$4,552,000 through a non-brokered private placement of 2,276,000 units of the Company at a price of \$2.00 per unit.

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 \$2.50 for a period of two years from the date of issuance, provided that if on any day that is 12 months following the date of issuance the 20-day volume weighted average trading price of the Company's shares on the TSX Venture Exchange equals or exceeds \$3.25, then upon the Company sending subscribers written notice of such date and issuing a news release announcing such date, the common share purchase warrants will only be exercisable for a period of 30 days following the date on which such written notice is sent to the subscribers.

In connection with the private placement, the Company paid a finder's fee equal to 6% of the gross proceeds and issued 85,040 compensation warrants exercisable for 24 months from the Closing of the Private Placement. Each warrant is exercisable into one common share and one warrant at a price of \$2.00. Each underlying warrant is exercisable into one common share at a price of \$2.50 for a two year period.

Management believes that cash on hand at September 30, 2011, and cash generated from the announced share offering will be sufficient to fund the Company's operations for at least 9 months. The continued successful commercial launch and generation of revenue in the 2012 fiscal years will extend this period.

## **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 June 15 2011, 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 focused 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 and \$10.7 million during fiscal 2008, 2009, 2010 and 2011, respectively. As of September 30, 2011, we had an accumulated deficit of \$44.2 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.

*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 at least the next 9 months. As such, we may need to raise substantial additional capital to:

- expand the commercialization of our products;
- manufacture our platforms in advance of placing them with our customers;
- fund our operations; and
- continue our research and development.

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 timely obtain additional funds on acceptable terms, 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.

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

We currently have one customer and 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.

***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, the European Conformity 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 timely obtain or maintain regulatory clearances or approvals, it would 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.

***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.

***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. 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.

***We may need additional capacity to meet our manufacturing needs at the end of 2012.***

Based on our microarray manufacturing forecasts, we expect that there is adequate capacity in our current location to expand our manufacturing capacity to meet our expected needs until the end of 2012. Until a facility upgrade is completed, we intend to undertake equipment upgrades to ensure sufficient manufacturing capacity to meet our expected requirements for commercial sales and our internal validation studies until the end of 2012.

***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 both 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.

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 Cleveland Clinic, Beth Israel Deaconess Medical Center, Hospital Clinic De Barcelona, University Hospital Maastricht, and The University of North Carolina at Chapel Hill. If any of 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 a material adverse effect on the timing of our future development efforts. In addition, we may not control the strategic partnerships in which we participate.

If any of our strategic partners terminate their relationship with us or fail to perform their obligations in a timely manner, or if we fail to perform our obligations in a timely manner, the development or commercialization of our technology in potential products may be affected, delayed or terminated.

***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 diagnostic platform and our microarrays. We do not have agreements with these key suppliers to that require them to supply us with components in the future. The loss of any of these key suppliers would require significant time and effort to locate and qualify an alternative source of supply. There are a limited number of suppliers who can manufacture the highly specialized equipment that forms a part of our SQiDworks system.

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.

***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, Claude Ricks, our Chief Financial 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.

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 and 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.

*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.

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;
- 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 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.

The Company's SQiDworks automated analytical platform and its lead IgX PLEX RA multiplexed test kit, which have received regulatory clearances in Canada, Europe and the United States, are believed to be the first microarray technologies in the autoimmune disease market to receive such clearances. The Company has continued to build on this regulatory success with the Health Canada licensing of its IgX PLEX Celiac Qualitative test and its IgX PLEX Celiac Quantitative test, also CE Marked in Europe. With the Health Canada approval for the first second generation fully quantitative assay, the Company anticipates that its quantitative celiac product line will progress commercially, in calendar 2012 with the release of a 6-plex quantitative panel that adds additional emerging biomarkers for markets in Canada, the US and Europe.

Our tests are designed to run only on the SQiDworks platform. In order to obtain approval for the SQiDworks platform and the Company's consumable tests for sale in the United States, our largest target market, the FDA typically requires the conduct of clinical validation studies to compare the performance of a new test to predicate tests currently approved for sale in the US. Upon successful completion of validation studies conducted at both SQi's labs and at multiple third party labs, the data derived are then presented to the FDA in the form of a 510(k) Pre-market Notification. It is typical for the external validation studies to take several months to complete and upon receipt of a completed 510(k) submission the FDA may take up to 180 days to render a decision on the application, not including any "time-outs" which the Company may take to prepare responses to various inquiries from the FDA. The Company believes the experience gained in obtaining the clearance of the SQiDworks, RA test and celiac test, will enable it to complete and file applications for clearance of the subsequently developed pipeline of assays more efficiently. This in turn may result in shorter review periods at the FDA than was experienced with the SQiDworks-RA system. The timing of such clearances is dependent on several factors some of which are not controlled by the Company.

During the current reporting period the Company did not earn significant revenues from its test kits or SQiDworks platform. Management believes that material revenues from the sale of its test kits may be achieved in the 2012 calendar year; this is subject to certain risks including without limitation, the continued success of the development program and regulatory approvals of the products. 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 Share Capital

As at September 30, 2011, there were 33,946,000 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 September 30, 2011:

Number of Warrants	Purchase Price	Expiry Date
1,199,000	\$ 4.00	December 4, 2011 (i)
237,000	\$ 1.90	December 23, 2011
1,140,000	\$ 5.00	August 12, 2012
57,000	\$ 2.50	August 12, 2012
<b>2,633,000</b>		

(i) Subsequent to the year ended September 30, 2011 the Company received approval from the TSX Venture Exchange to extend the expiry of these warrants to December 4, 2012.

The Company had the following stock options outstanding under the Plan at September 30, 2011:

Number of Options (000s)	Exercise Price	Expiry Date
58,000	\$ 1.20	November 25, 2011*
143,000	\$ 1.74	August 7, 2012
50,000	\$ 1.50	October 23, 2012
472,000	\$ 1.60	February 26, 2013
255,000	\$ 1.75	August 26, 2013
65,000	\$ 1.30	May 22, 2014
25,000	\$ 3.26	November 03, 2014
88,000	\$ 2.25	February 22, 2015
50,000	\$ 2.10	May 27, 2015
175,000	\$ 2.50	August 16, 2015
100,000	\$ 2.90	October 4, 2015
60,000	\$ 2.85	January 31, 2016
<b>1,541,000</b>		

\* These options were exercised subsequent to year end

## Off-Balance Sheet Arrangements

The Company has no off-balance sheet arrangements.

## Future Prospects

With the announced business realignment, management believes that the Company has the necessary intellectual, financial, and human capital to advance its targeted autoimmune test panels and the SQiDworks and SQiDLITE systems through the completion of clinical validation studies and regulatory filings in Canada, the U.S. and Europe. The Company also believes that these resources can be used to address the needs of and for the successful acquisition of customers in its Diagnostics Tools and Services offerings. Completing work and selling products and SQiD platforms to these customers could significantly increase the Company's revenues and could reduce the time to achieving revenues when compared to its core IVD business. The Company believes that its previous completion and approvals of its quantitative RA and celiac products and the current in-development performance of its quantitative celiac 6-plex and vasculitis products, as well as the early multiplexed performance of its proof of concept quantitative lupus 12-plex panel justifies the continued investment in development and commercialization of its in-development tests. It further believes that successful completion of these tests in development, and collaborations with its partners, may lead to the identification and commercialization of other test panels, not currently contemplated or in development, addressing unmet medical needs in the diagnosis or therapies for autoimmune, infectious disease and allergy management. Management believes that the performance of its approved products and that of its in-development products provides a basis for marketing to and winning customers in its Diagnostics Tools and Services business.

SQI's operational objectives are straightforward: generate revenue from products in the regulatory jurisdictions for which we have acquired regulatory approvals or licenses; generate revenue from services, products and software from customers in its Diagnostics Tools and Services business, 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.

The Company plans to execute on the following components of its operational strategy:

- Generate, maintain and grow customer sales in North America;
- Explore near-term revenue opportunities in Europe;
- Convert prospect customers in our Diagnostics Tools and Services business to revenue-generating customers
- Focus on commercialization and regulatory filings (where appropriate) for, fully quantitative second generation celiac 6-plex and vasculitis
- Expand our menu of IVD autoimmune tests through the completion of lupus, IBD-Crohn's, anti-TNF and other autoimmune tests;
- Work with our partners to enhance our product offerings and produce collaborative research identifying product strengths;
- Provide world-class customer support and service to ensure satisfaction; and,
- Publish scientific papers to broaden our product value proposition.

The Company will continue to invest in research and development activities related to its core platform technologies of microarray-based assays and detection devices.

## DISCLOSURE CONTROLS AND PROCEDURES, AND INTERNAL CONTROL OVER FINANCIAL REPORTING

The accompanying financial statements have been prepared by management in accordance with Canadian generally accepted accounting principles. 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 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 Canadian GAAP;
- (c) evaluated the design and effectiveness of the Company's DC&Ps as of September 30, 2011;
- (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 year ended September 30, 2011; 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.