

# **SQI Diagnostics Inc.**

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

**September 30, 2010**

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

*This discussion and analysis covers the audited financial statements for the years ended September 30, 2010 and 2009, 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 performed by management using information available as at January 18, 2011. Certain portions of this document including management's assessment of the Company's future plans and operations contain forward-looking statements that involve substantial known and unknown risks and uncertainties. These forward-looking statements are subject to numerous risks and uncertainties, some of which are beyond the Company's control, including the impact of general imprecision of reserve estimates, taxation policies, obtaining regulatory approvals, successful product development, competition from other producers, stock market volatility and the ability to access sufficient capital from internal or external sources. The Company's actual results, performance or achievement could differ materially from those expressed in, or implied by, these forward-looking statements and, accordingly, no assurance can be given that any of the events anticipated by the forward-looking statements will transpire or occur, or if any of them do so, what benefits that the Company will derive from them. Additional information relating to the Company is available by accessing the SEDAR website at [www.sedar.com](http://www.sedar.com) and the Company's website at [www.sqidiagnostics.com](http://www.sqidiagnostics.com).*

### **OVERVIEW**

SQI Diagnostics Inc. is a medical systems company that develops proprietary human diagnostic technology through multiplexing, miniaturization and automation. Our technologies enable laboratories to analyze multiple biomarkers simultaneously, deliver accurate and quantitative patient results in less time, significantly reduce labour costs, and increase profits when compared with current diagnostic instrumentation. The Company's proprietary SQiDworks™ instrument and IgXPLEX consumable tests together form an immunoassay system capable of providing many of the diagnostic tests currently performed in reference laboratories engaged in testing human blood for a wide range of disease markers.

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 IgXPLEX 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's strategy is to develop and commercialize test kits for the autoimmune disease market as further described below, and plans to pursue commercialization of tests in infectious disease and allergen testing in the future. The Company also plans to explore in-licensing opportunities to expand its product pipeline as well as to continuously improve its in-market product through the addition of novel biomarkers to the existing diagnostic panels of tests. To execute this strategy the Company plans to seek regulatory approvals to sell these additional tests globally starting with the North American markets. Following the successful

commercialization of several IgXPLEX test panels, management will evaluate selling in additional markets starting with countries in the European Union.

During the fiscal year ended September 30, 2010, the Company's strategic focus was to initiate the transition from a development Company to a commercial Company. During fiscal 2010, the Company entered into a contract with Gamma Dynacare Medical Laboratories (GDML) to supply them with a SQiDworks assay processing and analytical system and QuantiSpot RA™ test kits. GDML has also agreed to evaluate the Company's IgXPLEX Celiac test kits in the 2011 fiscal year and the Company expects to deliver validation IgXPLEX Celiac products to them in the second quarter of fiscal 2011. GDML is a key customer for the Company; it processes significant test volumes of both rheumatoid arthritis and celiac disease tests.

The Company is currently in the process of obtaining US FDA clearance of its IgXPLEX Celiac test. The Company believes the clearance of this product will significantly enhance its US market position. The Company is also following up with and is optimistic of winning additional Canadian customers based on Health Canada licensing of its IgXPLEX Celiac product during 2010.

The Company is focusing on the continued development of a pipeline of assays and SQiDworks and SQiDman assay processing and analytical platforms. The Company expects to advance additional test kits through the regulatory process during fiscal 2011 as discussed further in this document.

### Status of Development Program

The Company's development program includes several major components which the Company expects will advance its commercialization strategy. The status of each component is summarized and discussed in further detail below:

Product	Development Status	Approval Status		
		Canada	United States	Europe
SQiDworks	Complete	Approved	Cleared as a system with IgXPLEX RA	CE Marked
SQiDman	Development RUO	Not required	Not required	Not required
IgXPLEX RA	Complete	Approved	Cleared	CE Marked
QuantiSpot RA™	Complete	Approved		CE Marked
IgXPLEX Celiac	Complete	Approved	Filed	
IgXPLEX RA Quantitative	Development			

Product	Development Status
IgXPLEX Celiac Quantitative	Development
IgXPLEX TNF	Development
IgXPLEX Vasculitis	Development
IgXPLEX Lupus	Development
IgXPLEX IBD	Proof of Concept

1. The Company has developed fully automated SQiDworks 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 such platform to achieve these regulatory clearances.

The SQiDworks 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, Canadian regulatory approval for, and has CE Marked its IgXPLEX 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 Canadian regulatory approval for, and has CE marked, its fully quantitative QuantiSpot RA™ tests kits, run on the SQiDworks platforms. The QuantiSpot RA test kits provide fully quantitative information to further aid in the diagnosis and diagnostic monitoring of rheumatoid arthritis.

The Company has received Canadian regulatory approval for its IgXPLEX Celiac test kits and filed for US FDA regulatory clearance to market this product.

The Company’s SQiDworks and SQiDman platforms are also capable of running Research Use Only (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 customer’s 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.

2. The Company continues to focus on its in-market 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 IgXPLEX RA and IgXPLEX Celiac test panels. These improvements, requiring regulatory approvals, will represent second generation, fully quantitative IgXPLEX microarray technology and include expanded biomarker content for IgXPLEX RA and IgXPLEX Celiac. 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.

3. The Company has completed proof of concept for a multiplexed test to measure the presence of anti-TNF-based biologic drugs used to treat a variety of autoimmune diseases. The Company believes that a test to measure these biological drugs in patient serum will provide important clinical and treatment management tools for clinicians treating autoimmune diseases. The Company also believes that the development of this *companion diagnostic* product will be used as a basis to develop other companion diagnostic products that could be delivered and sold as RUO or IVO kits to a broader market including but not limited to the pharmaceutical development and academic research markets. During the year, the Company completed development of the prototype of the IgXPlex TNF and provided the prototype to its development partner, Mount Sinai Services (Toronto), to enable validation studies of the product and to provide initial performance feedback to the Company. The validation studies were completed, the performance criteria were met, and the Company's partner's feedback was received and is in the process of being implemented. The Company believes that it will deliver a commercial product to its partner during the 2011 calendar year.
4. During the fiscal year ended September 2010, the Company entered into an OEM development agreement with Silliker Inc. to complete development of a multiplexed botulism assay. Owing to SQI project prioritization, and minor changes to the scope of the project, the Company decided to hold development of this project. The Company, in association with Silliker will re-assess the viability of the project over the coming quarter and will prioritize it relative to the other development projects that are currently being focussed on.

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

During the year ended September 30, 2010, 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 to generate sales to targeted customers of the currently approved system, including the SQiDworks fully automated analytical platform, IgXPlex RA panel, QuantiSpot RA panel, and IgXPlex Celiac panel (Canada). The science, commercialization, and regulatory groups are focusing on the continued development of pipeline assays and SQiDworks and SQiDman platforms.

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

- (a) During the year ended 2010, the Company entered into a sales agreement with Gamma Dynacare Medical Laboratories (GDML) for the supply of its QuantiSpot RA test kits and SQiDworks platform. GDML has also requested that the Company provide to it sufficient IgXPlex Celiac test kits upon the Company's successful validation of the product such that GDML can perform its internal review of the product's performance. The Company expects to deliver these test kits to GDML during the second quarter of 2011. Successful internal review by GDML is expected to lead to the expansion of the current contract to include IgXPlex Celiac test kits;

- (b) Subsequent to the year ended September 30, 2010 the Company executed an evaluation agreement with a significant US-based reference laboratory and technology opinion-leader. The Company believes that the conversion of this target customer will result in a very positive general market reaction and demand for its products. The Company expects to deliver the SQiDworks platform to this target customer in the second fiscal quarter of 2011;
- (c) Completed an in-depth market survey of high potential target customers generating numerous high quality sales leads during the year;
- (d) Completed 50 sales calls with potential customers from our target list drawn from the top 100 diagnostic labs (based on volume) during the second, third and fourth quarters. The Company believes that it has generated significant interest from these target customers and that there is a high level of interest to evaluate the SQiDworks platform and available test kits upon the clearance of its IgXPLEX Celiac test kit;
- (e) Obtained the patent "Method to Measure Dynamic Internal Calibration True Dose Response Curves". Management believes this patent to be a significant achievement in its intellectual property portfolio establishing enhanced protection of in-array calibration and normalization; and,
- (f) Progressed a number of pipeline diagnostic tests through our discovery and development program;
  - (i.) the Company obtained clearance from the FDA to market and sell the IgXPLEX RA and SQiDworks system; the first ever cleared multiplexed/microarray product. Health Canada licenses were also obtained to market the IgXPLEX RA product in addition to the previously licensed QuantiSpot RA product and SQiDworks platform;
  - (ii.) Applied for and obtained Health Canada license to market the IgXPLEX Celiac 4- PLEX panel;
  - (iii.) Applied for US FDA regulatory clearance of its IgXPLEX Celiac 4- PLEX panel. Subsequent to the fiscal year ended September 30, 2010, the Company received and responded to questions from the FDA regarding this panel. The questions and responses are described by the Company as those expected in the normal course of its regulatory processes. ;
  - (iv.) Based on market information obtained through in-depth market surveys and sales calls with potential customers the Company has identified enhancements to its existing RA and Celiac products. These enhancements, requiring regulatory approvals, are in development and include transition from qualitative to fully quantitative reporting and the expansion of additional biomarkers that the Company believes will be relevant in the market.
  - (v.) The IgXPLEX Vasculitis assay was advanced to the Assay Development stage and is expected to complete clinical validation in the second quarter of 2011.
  - (vi.) Advanced the IgXPLEX Lupus test kits to the proof of concept stage and subsequent to the year end it was progressed to the assay development stage. The Company expects to initiate clinical validation of this product in the second calendar quarter of 2011, and complete regulatory filings shortly thereafter.

- (vii.) IgXPLEX IBD was progressed into the proof of concept stage and is being actively developed with the expectation of being completed and filed for regulatory approvals in 2011.
- (viii.) Continued development of IgXPLEX TNF test kits based on the expanded performance requirements requested by our partner, Mount Sinai Services. During this time, the R&D team also made significant technical improvements in the assay. The IgXPLEX TNF test is intended to be used to measure and monitor the concentration of anti-TNF-based drugs including Remicade™, Humira™ and Enbrel™ in patients with a range of autoimmune and inflammatory disorders including but not limited to rheumatoid arthritis, crohn's disease, plaque psoriasis and ankylosing spondylitis. The Company believes that the cost-effective measurement of these drugs would provide clinicians enhanced treatment options. The Company expects that it will be able to complete commercialization of an IgXPLEX TNF test that will be able to be cleared for IVD sale in Canada. It will remain as a Research Use Only (RUO) product with limited performance claims in the US until expanded clinical studies are performed. However, the Company continues to believe that, as there are no predicate tests currently approved to test for the presence and concentration of anti-TNF, there is a viable RUO market for the product in the US.
- (ix.) Initiated platform development for SQiDman with a target to complete development that is expected to coincide with customer requirements for potential research use collaborations. Subsequent to the year end this SQiDman platform became available for RUO/IUO applications. This platform is currently not targeted at IVD applications until the Company is actively developing infectious disease content and at that time the SQiDman platform would require additional development for regulatory requirements;

**(g) Partnering Successes in 2010**

During and subsequent to the year ended 2010, the Company was successful in entering into multiple collaboration agreements with the leading institutes highlighting the market interest in multiplexing and the Company's achievements to date. These collaborations significantly improve the Company's ability to progress its products through the development process through obtaining access to patient sera needed for assay development, verification of in-development products and final product clinical validation.

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

Partnering Institute*	Principal Investigator	Pipeline Product	Purpose
Cleveland Clinic (i)	Dr. Tubbs	IBD	Serum Samples Collaboration
Beth Israel Deaconess Medical Center	Dr. Kelly	Celiac	Serum Samples Collaboration/Publication
Beth Israel Deaconess Medical Center	Dr. Moss	Anti-TNF	Serum Samples Collaboration/Publication
Hospital Clinic de Barcelona, Spain	Dr. Cervera	Vasculitis	Serum Samples Collaboration/Publication
Cleveland Clinic	Dr. Wang	All Rheumatoid Arthritis Various	Clinical Validation Collaboration Serum Samples
University of Maryland	Dr. Fasano	Celiac	Serum Samples
University Hospital Maastricht, the Netherlands	Dr. Damoiseaux	Vasculitis	Serum Samples Collaboration
University North Carolina Kidney Center (ii)	Dr. Falk	Vasculitis	Collaboration Serum Samples Clinical Validation

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

- (i.) Completed an “IBD Multiplex Panel Development Collaboration” agreement with Dr. Tubbs of the Department of Molecular Pathology, Cleveland Clinic. This agreement gives the Company access to a significant resource for professional collaboration of its IBD (Crohn’s Disease) IgXPLEX product and next generation biomarkers as well as access to a valuable bank of characterized patient serum for development and clinical validation.
- (ii.) Subsequent to the fiscal year end, the Company entered into a clinical validation agreement with the University North Carolina Kidney Center (UNCKC), Chapel Hill, with Dr. Falk acting as the principal investigator. This agreement gives the Company access to a significant bank of prospective and stored patient serum samples for characterized positive vasculitis patients. These serum samples

substantially improve the Company's ability to develop and validate its IgXPlex Vasculitis product. The collaboration agreement also provides the Company professional expertise from the world leader in diagnosing vasculitis disease. The Chapel Hill Protocol is the most recognized diagnostic algorithm used to diagnose vasculitis disease. As part of the agreement, the Company is collaborating to establish a center of excellence for microarray-based multiplex testing of vasculitis with Dr. Falk through the collaboration and delivery of a SQiDworks platform at Chapel Hill. The agreement calls for co-publishing of the results of the collaborative efforts.

The Company anticipates that this platform can be used for expanded purposes alongside the collaboration with Dr. Falk including, but not limited to validation of additional products in its pipeline.

### **Corporate Financing Transactions**

During the fiscal year ended 2010 the Company was successful in raising significant capital to sustain its operations from the exercise of warrants and options and from two private placements, in total generating \$13,997,000 in net cash.

On December 04, 2009, the Company completed a private placement resulting in the issuance of 2,398,104 units at a price of \$2.75 per share for gross proceeds of \$6,595,000 (net of cash costs - \$6,109,000). Each unit was comprised of one common share and one half common share purchase warrant. Each whole warrant entitles the holder to purchase one additional common share at a price of \$4.00, expiring December 4, 2011. The total share issuance costs were \$611,000.

On August 12, 2010, the Company complete another private placement resulting in the issuance of 2,280,000 units at a price of \$2.50 per unit for gross proceeds of \$5,700,000 (net of cash costs - \$5,399,000). Each unit was comprised of one common share and one half common share purchase warrant. Each whole warrant entitles the holder to purchase one additional common share at a price of \$5.00, expiring on August 12, 2012. The total share issuance costs were \$363,000.

During the fiscal year ended 2010 199,493 warrants with an expiry of April 26, 2010 were exercised resulting in the issuance of 199,493 shares and net proceeds of \$120,000. During the fiscal year ended 194,200 warrants with an expiry of June 3, 2010 were exercised resulting in the issuance of 194,200 shares and net proceeds of \$291,000. In addition, 576,563 warrants with an expiry date of June 29, 2010 were exercised resulting in the issuance of 576,563 shares and net proceeds of \$1,384,000 the remaining 1,207,213 warrants with an expiry date of June 29, 2010 expired unexercised.

During the fiscal year ended 2010 the Company also issued 916,683 shares resulting from the exercise of options (850,017 of these option were issued under the Stock Option Plan). The exercise of these options resulted in gross proceeds of \$694,000.

## CRITICAL ACCOUNTING POLICIES AND SIGNIFICANT ESTIMATES

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. Patents and trademarks are recorded net of accumulated amortization of \$627,000 (September 30, 2009 - \$527,000).

### **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, 2010, the Company was in development of its 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 and 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 ITC's receivable, valuation of stock options and warrants and valuation allowance on future tax assets.

## Recent 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 is currently evaluating the new sections to determine the potential impact of any future transactions on its consolidated financial statements.

## International Financial Reporting Standards (IFRS)

The CICA plans to converge Canadian Generally Accepted Accounting Principles with International Financial Reporting Standards (“IFRS”) over a transition period expected to end in 2011, when IFRS will be fully adopted. The Company will be required to adopt IFRS for its 2012 fiscal year end and will be required to provide IFRS comparative information for the previous fiscal year. The Company continues to monitor and assess the impact of the convergence of Canadian GAAP and IFRS on its financial statements. We have identified the main differences between existing Canadian GAAP and IFRS standards. 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	Difference with potential impact on the Company
IFRS 1 First time adoption of IFRS	The Company is in the process of selecting the applicable exemptions under IFRS. Required 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.
IAS 16 Property Plant and Equipment	The Company will re-evaluate the useful life of each component of property plant and equipment and will restate, if applicable, the historic amortization expense.
IAS 36 Impairment of Assets	The Company will evaluate potential impairments using discounted cash flow analysis as required under 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.
IFRS 2 Share based payments	The Company will treat all options with graded vesting as separate option awards as required under IFRS 2. The Company will utilize the exemptions under IFRS 1 when converting to the new standard.
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.

## SELECTED FINANCIAL INFORMATION

The table below summarizes annual financial information for the fiscal years ending September 30, 2010 and 2009. Certain comparative information has been reclassified to conform to the current year's presentation.

	Year ending September 30, 2010 (000s)	Year ending September 30, 2009 (000s)
<b>Revenue</b>	\$ 35	\$ 32
<b>Net loss</b>	\$ 8,073	\$ 5,910
<b>Net loss per share</b>	\$ (0.27)	\$ (0.23)
<b>Weighted average shares</b>	30,349	25,158
<b>Total Assets</b>	\$ 13,134	\$ 6,205

The increasing net loss trend between the year ended September 30, 2009 and the fiscal year ended September 30, 2010 was primarily related to increased development activity and expenses for the scientific discovery and development of several IgXPLEX assays, the regulatory approval, and the commercialization of the QuantiSpot RA, IgXPLEX RA and IgXPLEX Celiac test panels and SQiDworks system. In addition a number of diagnostic tests continued progression through our discovery and development program including IgXPLEX Vasculitis and, IgXPLEX SLE (Lupus), IgXPLEX TNF and initial development of SQiDman. The Company also invested in the development of its second generation fully quantitative and expanded biomarker panels for IgXPLEX RA and Celiac products as previously discussed.

Differences in the net loss for 2010 versus 2009 were also related to increased professional and consulting fees including recruiting fees for personnel additions, legal and accounting fees, increased stock-based compensation expenses, and expansion of infrastructure resulting in increased personnel and occupancy costs in the year ended September 30, 2010.

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 \$ 5,354,000 for the year ending September 30, 2010 compared to \$3,449,000 for the year ending September 30, 2009. The principle difference in Gross R&D expenses of \$1,905,000 between the two periods was due to:

- an expansion of development activities owing to an expanded number of autoimmune products in advanced stages of development in 2010 compared to 2009. During 2009 IgXPLEX RA and Celiac were in the development stage with 2 other panels in early discovery. During 2010 the company advanced IgXPLEX Celiac to the regulatory approval stage, obtained the regulatory approval of IgXPLEX Celiac in Canada, had 5 additional panels in the development stage (second generation IgXPLEX Celiac and RA, IgXPLEX Vasculitis, IgXPLEX Lupus, and IgXPLEX TNF) and one product in the early discovery stage (IgXPLEX IBD);

- Initiated development efforts toward the SQiDman platform and enhancements to the SQiDworks platform and software allowing multi-plate/multi-product runs, pick and pay capability and Lab Information Management Systems (“LIMS”) integration;
- a greater level of activity and personnel additions in 2010 to complete the required work;
- cost related to Autoimmune assay validation services;
- new expenditures for internal and third party clinical studies including increased acquisition costs for patient serum tested in these studies.

In the fiscal period ending 2010 the Company had a peak of 53 employees, 44 involved directly in R&D compared to the 2009 fiscal year when the Company had a peak of 36 employees with 29 involved directly in R&D. R&D salaries and payroll costs increased from \$2,372,000 for the period ending September 30, 2009 to \$3,159,000 for the year ending September 30, 2010. R&D consumable costs rose in proportion to the number of R&D employees and development projects being prosecuted, and these expenses increased by \$1,118,000 in the year ending September 30, 2010 above the expenses incurred in the period ending September 30, 2009.

Gross R&D expenses were offset by the recognition of Scientific Research and Experimental Development (“SRED”) cash refunds received in the 2009 fiscal year of \$87,000 resulting in net R&D expenses of \$3,362,000 and by \$295,000 in the 2010 fiscal period resulting in net R&D expenses of \$5,059,000.

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, 2010 compared to the period ending September 30, 2009 from \$447,000 to \$471,000. The primary reasons for the \$24,000 increase were an increase in travel related to corporate development activities, increased occupancy costs due to the increase in the number of employees, and other costs related to the general growth of the corporate activities and related overheads to operate the business. General and administrative expenses included a \$97,000 patent write down in 2009; there was no similar write down in the current year. Amounts for sales and marketing included in general and administrative expenses in the prior year have been reclassified to sales and marketing expenses

Sales and marketing costs were primarily related to sales and marketing consultant fees and to travel related to selling activities. Sales and marketing expenses totalled \$474,000 for the year ended September 30, 2010 compared to \$409,000 for the year ended September 30, 2009. The increase of \$65,000 was primarily a result of additional consultant costs as the company expanded its commercialization efforts.

## Fourth Quarter Commentary

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

	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	\$ 1,811	\$ 2,021	\$ 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

	September 30, 2009 (000s)	June 30, 2009 (000s)	March 31, 2009 (000s)	December 31, 2008 (000s)
Revenue	\$ 7	\$ 8	\$ 7	\$ 10
Net Loss	\$ 1,616	\$ 1,354	\$ 1,473	\$ 1,467
Net Loss Per Share	\$ (0.06)	\$ (0.05)	\$ (0.06)	\$ (0.07)
Weighted Average Shares	27,271	26,326	25,837	22,448

Revenue for the quarter ended September 30, 2010 was \$14,000 compared to \$7,000 for the quarter ended September 30, 2009. In the last quarter of 2010 the Company completed its first sale of its QuantiSpot RA test kit to a 3<sup>rd</sup> party. Other revenue for the three month periods ending September 30, 2010 and 2009 was from service-based revenue provided to a related party.

For the quarter ended September 30, 2010, the Company recorded a net loss of \$2,621,000 (\$0.08 net loss per share) compared to a net loss of \$1,616,000 (\$0.06 net loss per share) for the quarter ended September 30, 2009. Per share values are based on the weighted average shares outstanding in the period. For the quarter ended September 30, 2010 there was an average of 32,705,000 shares outstanding.

Net loss and net loss per share were greater for the quarter ended September 30, 2010 compared to September 30, 2009. The increased loss for the three months ending September 30, 2010 was primarily related to increases in activity and expenses in the discovery efforts for and development of several IgXPLEX assays, including ordinary increases in wage and wage-related expenses owing to an increase in personnel, increased lab expenditures to support the greater number of projects, and other direct costs including serum acquisition and development and validation partner costs. Sales and Marketing expense was higher in the quarter ended 2010 owing to additional travel and contract resources in sales and marketing as the Company increase its sales effort for approved IgXPLEX panels in Canada and the United States and in anticipation of further approval.

R&D expenditures for the three month period ended September 30, 2010 were \$1,621,000 compared to the \$872,000 (before the effect of SR&ED tax credits) for the three month period ended September 30, 2009. The increase in R&D expense for the three month period ended September 30, 2010 compared to the three months ending September 30, 2009 resulted from

increased R&D activity with an increased number of assay panels in development and to regulatory validation efforts related to the IgXPLEX Celiac assay. In the fourth quarter of 2009 the Company had 1 panel in development and one panel in the regulatory approval process. In the last quarter of 2010 in addition to the IgXPLEX Celiac assay in regulatory validation, the company had 5 panels in development and 1 additional panel in early discovery and development. The company has also expended developments efforts toward the SQiDman platform and enhancements to the SQiDworks platform and software. The company also incurred costs related to autoimmune assay validation services and expenditures for internal and third party clinical studies.

Corporate expenses 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. General and Administrative expenses include facility costs, insurance costs, and foreign exchange expenses. Corporate and general expenses totalled \$299,000 for the quarter ended September 30, 2010 compared to \$290,000 for the quarter ended September 30, 2009. During the fourth quarter of 2010 corporate expenses increase as a result of higher salary costs, including bonuses and increased personnel and increased occupancy costs. Corporate expenses included a write down for abandoned patents in the quarter ended September 30, 2009, there was no similar write down in 2010.

Professional consulting (legal, accounting, Board of Directors compensation, recruiting, administrative contractor, and investor relations) costs in the quarter ended September 30, 2010 were \$223,000 compared to \$179,000 from the quarter ended September 30, 2009. The increase in professional and consulting costs in the quarter ended September 30, 2010 were primarily related to the use of multiple experts in the areas of professional recruiting for science, regulatory, engineering and technical professionals, laboratory cost analysis, competitive and product intelligence, and work-flow management. Professional recruiting costs were incurred primarily to increase staffing to support product pipeline and commercialization efforts. Amounts for sales and marketing included in professional and consulting expenses in 2009 been reclassified to sales and marketing expenses to conform with the current year's presentation.

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 \$165,000 for the quarter ended September 30, 2010 compared to \$82,000 for the quarter ended September 30, 2009. The increase in sales and marketing expenses were primarily related to additional consulting costs paid to increase staffing to support product pipeline and commercialization efforts.

Operational expenses were partially offset by interest income earned on short-term investments. The interest income was \$32,000 and \$12,000 for the year and quarter ended September 30, 2010 respectively. The interest earned for the year and quarter ended September 30, 2009 was \$121,000 and \$3,000. Interest in 2009 included interest earned on ITC credits outstanding. 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 \$218,000 for the quarter ended September 30, 2010 (\$402,000 - year ended September 30, 2010) compared to \$89,000 for the quarter ended September 30, 2009 (\$380,000 - year ended September 30, 2009). The related stock option issuances are described further below in the Outstanding Share Capital section.

## Outlook

Management expects losses to continue for the current fiscal year as investment continues in product development and commercialization efforts on its pipeline of autoimmune test kits as well as investment in sales and marketing. During the 2011 fiscal year the Company will focus on sales and placing SQiDworks systems in Canadian and US-based customers for system evaluation and expects that of the majority of these evaluation placements will lead to commercial acceptance and revenues from sales of consumable test kits. The Company delivered one such evaluation placement in January 2010 to GDML. This system was installed and handed off to the customer in February following training of its operational personnel. From the date of hand-off the customer was provided 90 days to run its internal acceptance validation. During the quarter ending June 30, 2010, the Company converted the positive validation of the platform to a commercial agreement for commercial use by the customer, and generated revenue to the Company in the quarter ended Sept 30, 2010.

During the 2010 fiscal year the Company utilized its significant positive customer feedback relating to the commercial feasibility of its system and consumable tests from this market survey generated in the first two quarters of the 2010 fiscal year to focus on high-value customers with higher volumes of rheumatoid arthritis testing. Based on this market feedback, the Company believes that its strategy of focusing development, commercialization and marketing efforts on panels of autoimmune assays targeted at medium and large reference laboratory customers continues to be sound and aligns with customer demand. As well, the Company generated a significant number of qualified sales leads from its survey activity and is in the process of conducting both initial and follow-up sales meetings with approximately 50 qualified prospective customers.

Our analysis of the market would indicate that there are over 315 laboratories in the United States with sufficient volume of rheumatoid arthritis testing to be target customers for the SQiDworks / IgXPLEX RA system. Management believes that the addressable market is sufficiently large and that with the completion of additional IgXPLEX panels, including IgXPLEX Celiac, licensed in Canada and currently under FDA review, the company will be well-positioned for wider scale commercial acceptance of our platforms during the 2011 fiscal year, and beyond. Management believes the number of potential customers upon regulatory clearance of multiple IgXPLEX products (ex IgXPLEX RA and IgXPLEX Celiac) in the US, to greatly exceed those currently targeted with only one approved product in the US. Further, completion of SQiDworks Lite in 2011 for IVD and RUO/IUO applications will greatly enhance the addressable market into the 1,000s of potential customers.

Based on its successful FDA clearance, its Health Canada licenses and EU authorization, management increased the intensity of the development and commercialization of several new IgXPLEX test kits in 2010 and expects this development to result in the submission of a continuous flow of autoimmune test kit applications to the US, Canadian and EU regulatory bodies during the 2011 calendar year. This activity will generate similar R&D expenses in 2011 as was experienced in the second half of the 2010 fiscal year related to internal development, internal verification and validation studies and third party validation studies. This activity is expected to continue in the foreseeable future as the company completes the autoimmune pipeline, continues to improve in-market tests and initiates development in new clinical areas.

During the 2011 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 that have an interest in companion testing during drug development and that are targeted in our clinical areas of interest. The Company would target lower throughput customers

conducting research with SQiDman platform and RUO/IUO products, higher throughput customers with our SQiDworks platform or SQiDworks Lite, the Company's intermediate platform expected to start in development in the first half of calendar 2011 and anticipated to be completed with nine months after initiation. Management believe that SQiDworks Lite will be an important system for future clinical areas and non-reference lab customers. SQiDworks Lite is expected to be fully automated, allow smaller batch sizes and to have equivalent analytical performance when compared to the current fully automated SQiDworks Platform.

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 are successful in growing our placement of SQiDworks platforms across Canada and the United States, and increase our product menu available to our customers. Management will add these expenses as needed to support forecasted customer installations of SQiDworks platforms and sales of consumable kits.

Management will continue to monitor the cash burn rate in relation to the capital available to it and will manage cash flows as required in the context of the capital markets. Management believes that it may, at some point, seek additional capital to advance and accelerate the number of tests under development and being validated for regulatory submissions, to expand our areas of focus beyond autoimmune disease at the appropriate times, expand our fully marketed analytical platform system portfolio enabling us to address a broader market, to build SQiDworks platforms to address customer demand, as well as to expand our sales team and its efforts in the United States and other jurisdictions as appropriate.

### **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, 2010 is \$49,000 (September 30, 2009 - \$50,000), related to recovery of occupancy costs, from a corporation in which an officer of the Company was also an officer. Consulting fee revenue of \$30,000 for the year ended September 30, 2010 (year ended September 30, 2009- \$27,000) was earned from this corporation. At year end, \$1,000 (September 30, 2008 - \$6,000) due from this corporation is included in amounts receivable.

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

Operational activities for the year ended September 30, 2010 were financed by cash on hand.

During the year ended September 30, 2010 the Company:

1. Completed two non-brokered private placement for combined gross proceeds of \$12,295,000 through the issuance of 4,678,000 shares; and,
2. Received net proceeds of \$1,795,000 following the exercise 970,256 warrants resulting in the issuance of 970,256 shares.
3. Received \$694,000 for new shares issued upon the exercise of 916,684 options.

At September 30, 2010, current assets were \$9,902,000 compared to \$3,649,000 at September 30, 2009. Working capital as at September 30, 2010 was \$8,928,000 compared to \$3,280,000 at September 30, 2009.

Management believes that cash on hand at September 30, 2010, and cash generated from revenues will be sufficient to fund Company operations for at least 12 months. The continued successful commercial launch and generation of revenue in the 2011 fiscal years will extend this period.

## Risks

The Company is subject to various risks. Factors that could cause results or events to differ materially from management's current expectations include, but are not limited to:

- changing competitive technology and market conditions;
- the Company's ability to successfully commercialize additional IgXPLEX tests in the autoimmune disease market;
- the successful and timely completion of clinical validation studies at partner sites;
- the failure to obtain requisite regulatory approvals (including the clearance of the FDA) for the Company's diagnostic tests in a timely manner, if at all, and other inherent uncertainties related to the regulatory approval process;
- the ability to generate sufficient acceptance of the Company's platforms and sales of test kits; and,
- the ability of the Company to fund its cash requirements from internal and external sources.

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 IgXPLEX RA test kit used to detect and quantify a panel of biomarkers to aid in the diagnosis of rheumatoid arthritis was cleared and licensed to be sold and marketed in Canada during the quarter ended December 31, 2008 and in the United States in November of 2009, and in the quarter ended March 31, 2009 were authorized to be CE Marked and to be sold in Europe. To the best of the Company's knowledge, this was the first and remains the only multiplexed microarray test in the autoimmune disease market to have been successfully cleared by the FDA or, in combination with IgXPLEX Celiac, the only tests of this nature licensed in Canada. The Company sought regulatory approvals and clearances for its IgXPLEX Celiac test kit in the fourth quarter and received Health Canada approval prior to year end. The Company is awaiting FDA clearance.

IgXPLEX and QuantiSpot 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- IgXPLEX RA system will enable it to complete and file applications for clearance of subsequently developed pipeline IgXPLEX assays more efficiently. This in turn may result in shorter review periods at the FDA than was experienced with the SQiDworks-IgXPLEX RA system. The timing of such clearances is dependent on several factors some of which are not controlled by the Company.

The IgXPLEX multiplexed test panels used to detect and quantify a panel of biomarkers to aid in the diagnosis of lupus, vasculitis, and Crohn's disease, are currently in the Company's discovery and development pipeline along with the IgXPLEX TNF panel to detect the drug, anti-TNF, that is used in the management of multiple autoimmune diseases. The IgXPLEX TNF panel is used to measure the quantity of therapeutic agents in the body and the information from this test could be used by clinicians in the management of several autoimmune diseases, including but not limited to rheumatoid arthritis, vasculitis and irritable bowel disease.

The Company is expecting one, or all of its pipeline of new multiplexed test panels in the autoimmune disease market under development (Vasculitis, Lupus, IBD (Crohn's), and the second generation and expanded IgXPLEX RA and Celiac tests, and the SQiDworks platform, together each a system, to be commercially ready to file applications with the applicable regulatory jurisdictions in calendar 2011. Management believes that the IgXPLEX TNF test kits will be available for commercial sale for diagnostic use in Canada and research use in the US prior to the end of the 2011 calendar year.

During the current reporting period the Company did not earn material revenues from its test kits or SQiDworks platform. 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. Management believes that it has sufficient cash reserves to support the development, validation and commercialization of Vasculitis, Lupus, IBD (Crohn's), and the second generation and expanded IgXPLEX RA and Celiac tests and SQiDworks in North America.

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, 2010, there were 33,758,000 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, 2010:

Number of Warrants	Purchase Price	Expiry Date
144,000	\$ 2.750	December 4, 2010
107,000	\$ 1.250	January 22, 2011
1,199,000	\$ 4.000	December 4, 2011
237,000	\$ 1.900	December 23, 2011
1,140,000	\$ 4.000	August 12, 2012
57,000	\$ 2.500	August 12, 2012
<b>2,884,000</b>		

The Company had the following stock options outstanding under the Plan at September 30, 2010:

Number of Options (000s)	Exercise Price	Expiry Date
33,000	\$ 1.200	June 29, 2011
67,000	\$ 1.200	August 29, 2011
180,000	\$ 1.740	August 7, 2012
50,000	\$ 1.500	October 23, 2012
758,000	\$ 1.600	February 15, 2013
269,000	\$ 1.750	August 26, 2013
80,000	\$ 1.300	May 21, 2014
25,000	\$ 3.260	November 03, 2014
68,000	\$ 2.250	February 22, 2015
60,000	\$ 2.100	May 27, 2015
175,000	\$ 2.500	August 16, 2015
<b>1,764,000</b>		

## Off-Balance Sheet Arrangements

The Company has no off-balance sheet arrangements.

## Future Prospects

In its current state of evolution, management believes that the Company has assembled the necessary intellectual, financial, and human capital to advance its current pipeline of autoimmune test panels and the SQiDworks system through the completion of clinical validation studies and regulatory filings in Canada, the U.S. and Europe. The Company believes that completion of its lead product IgXPLEX RA and its clearance in the United States plus the filing

for clearance in the United States of IgXPLEX Celiac, the licensing in Canada of QuantiSpot RA, IgXPLEX RA and IgXPLEX Celiac, and authorization to CE Mark it in Europe of QuantiSpot RA justifies the current intensified investment in development and commercialization of its pipeline of an additional group of at least eight autoimmune microarray diagnostic panels over the next eighteen months, with four novel and two second generation tests currently in the Company's discovery or assay development processes. It further believes that successful completion of these pipeline tests may lead to the development and commercialization of other test panels addressing unmet medical needs in the detection of known analytes used in the diagnosis or therapies for autoimmune, infectious disease and allergy management.

SQI's operational objectives are straightforward: generate revenue from products in the regulatory jurisdictions for which we have acquired regulatory approvals or licenses; continued successful commercialization and continuous improvement of a menu of autoimmune test kits; and, expansion of partnerships and other strategic relationships to enhance our product offerings or 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;
- Complete commercialization and regulatory filings (where appropriate) for, vasculitis, lupus, IBD, anti-TNF and second generation product extensions for RA and Celiac panels;
- Work with our partners to enhance our product offerings;
- 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 the quarter ended September 30, 2010;

(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, 2010; 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.