

# **SQI Diagnostics Inc.**

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

**September 30, 2009**

## 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, 2009 and 2008, 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 20, 2010. 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 in multiplexing, miniaturization and automation. We provide laboratories the ability to simultaneously analyze multiple biomarkers, deliver accurate and quantitative patient results in less time, significantly reduce labor, and increase profits when compared with current diagnostic instrumentation. The Company has received clearance from the United States Food & Drug Administration ("FDA") (subsequent to the September 2009 fiscal year end), Canadian regulatory approval for, and has CE Marked its SQiDworks platform together with 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 is developing and commercializing other test kits for the autoimmune disease market as described further below, and plans to pursue commercialization of tests in infectious disease and allergen testing in the future. The Company plans to seek regulatory approvals and clearances to sell these additional tests globally starting with the North American markets and Europe.

The Company's proprietary SQiDworks™ instrument and 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 will provide to the laboratory diagnostic testing market:

- (a) Fully and semi-automated, microarray-based test platforms enabling laboratory customers to generate multiple patient results with one unit of 'test effort', and

- (b) A menu of tests to support a wide range of disease diagnoses in each of the disease segments we are targeting. The Company's first launch market is in the autoimmune disease segment with its qualitative IgXPLEX RA™ and quantitative QuantiSpot RA™ multiplex panels for aiding in the diagnosis of rheumatoid arthritis. The Company is developing additional test kits within the autoimmune disease segments including but not restricted to tests that aid in the diagnosis of celiac disease, vasculitis, lupus, and Crohn's disease, and antiphospholipid syndrome (APS). Other autoimmune disease, infectious disease and allergen panels are expected to follow. The Company believes that the approved IgXPLEX RA and QuantiSpot RA tests have provided a template for the rapid development and commercialization of subsequent autoimmune panels. The majority of the development efforts for each subsequent assay panel and the SQiDworks system rely heavily on the infrastructure of the prior assay construct and this infrastructure does not require additional development.
- (c) The Company has also completed proof of concept for a test to measure the presence of biologic drugs used to treat a variety of autoimmune diseases. The Company believes that a test to measure these molecules in patients will provide important clinical and treatment management tools for autoimmune diseases. Subsequent to the period end the Company completed development of the prototype of this test and provided its partner with the results of verification of the assay. The Company believes that it will deliver a prototype of this test to its partner for evaluation of the commercial product by the end of the second fiscal quarter. Following evaluation and feedback on the assay's performance the Company and its partner will determine the next steps for commercial roll-out of the IgXPLEX IA (infliximab assay).
- (d) The Company also completed the discovery phase milestones under contract for a panel to detect multiple analytes used to aid in the detection and diagnosis of botulism infection in partnership with Silliker Inc., a subsidiary of BioMeriux. Subsequent to the period end the Company was completing negotiations of a development and supply agreement wherein it is contemplated that the Company will complete commercialization of the IgXPlex BotX™ panel and deliver this to Silliker Inc. in the 2010 calendar year.

From 2003 to present, the Company has been primarily involved in research, development and initial commercialization activities related to its core technology platform (together SQiDworks™ and QuantiSpot™). 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 also incurred costs associated with gathering market intelligence from prospective customers and in fostering partnership opportunities with potential novel biomarker collaborators and OEM device manufacturers. During the fiscal year ending September 30, 2009 the Company has invested in its sales and marketing team and infrastructure. This sales effort is focusing on the North American market to generate sales with the currently approved system including the SQiDworks™ fully automated analytical platform, IgXplex RA panel and QuantiSpot RA™ panel. The Company will also pursue, where appropriate, investment in its novel IgXplex and QuantiSpot assays (QuantiSpot IA and QuantiSpot BotX).

#### **Commercial Development Current Status**

During the year ended September 30, 2009, the Company completed internal validation and multi-site, external validation studies for its SQiDworks platform, IgXplex RA™ and QuantiSpot RA test kits. Successful completion of these validation studies lead to the Company filing

submissions seeking clearance from the FDA to market and sell the products; for licenses from Health Canada to market and sell the products in Canada; and, authority to CE Mark the products for sale in the European Union. During the year ended September 30, 2009 the Company received its FDA clearance to market its SQiDworks/IgXplex RA system, license from Health Canada clearing it to market and sell the SQiDworks platform with the QuantiSpot RA and IgXplex RA test kits in Canada as well as self-certifying to CE Mark and sell the SQiDworks/QuantiSpot RA system in Europe. The information below provides an overview of the Company's achievements during the year ended September 30, 2009:

- Submitted FDA 510(k) Pre-Market submission and subsequent to the year-end received clearance for the SQiDworks™ Platform and IgXplex RA kit, together a system
- Submitted application and received Health Canada license for the SQiDworks™ Platform and QuantiSpot RA and IgXplex RA kits;
- Received CE Mark authorization for the QuantiSpot RA kit and SQiDworks Platform;
- Progressed a number of pipeline diagnostic tests through our discovery and development program.
  - Celiac 4-plex panel was moved from proof of concept into commercial development. Subsequent to the period end the Celiac 4-plex panel completed verification and was staged for external validation, expected to be complete by the end of March 2010.
  - Vasculitis entered into the proof of concept process and is expected to advance to development verification stage by the end of the second fiscal quarter of 2010.
  - Anti-TNF was moved into discovery and is expected to be mid-way through the development phase in the fourth fiscal quarter of 2009. The successful commercialization of the Anti-TNF product would result in a research use only (RUO) initial release by the end of the second fiscal quarter of 2010.
  - RA 5-plex is an expansion on our RA 4-plex product and adds an additional biomarker to the panel; this panel is currently staged for verification and external validation.
- Filed four patents including:
  - IgX-Plex™ and IVDplus plex™ technologies with the potential to secure our technological advantage on antibody sub-class multiplexing;
  - Synthetic protein mimetic molecules to optimize multiplex binding and increasing specificity;
  - A method to increase fluorescent signal intensity of microarray matrices;
  - A two-phase method to optimize microarray surfaces and vapour content thus improving fluorescent signal and ultimately improving assay sensitivity;
- Subsequent to the year-end were granted 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 and is critical to the protection of in-array calibration and normalization.

- Filed trademarks to support new branding IgX-Plex™ and IVDplus plex™ to support our competitive differentiation;

Subsequent to the year end and in the first calendar quarter of 2010, the Company entered into an evaluation agreement and installed a SQiDworks platform at a major Canadian reference laboratory. Under the terms of the agreement the customer will have 90 days to evaluate the performance of the SQiDworks system for use with the Company's test panels for aiding in the diagnosis of rheumatoid arthritis. Upon successful completion of the evaluation the customer will have the right, but not the obligation to begin purchasing consumables for its commercial purposes.

### **Corporate Financing Transactions**

In May, 2008 the Company entered into a financing arrangement with the Royal Bank of Canada to borrow \$730,000 in a non-revolving term credit facility. The interest and principal were originally due by November 30, 2008, or upon receipt of 2006 and 2007 SR&ED investment tax credit refund, whichever was sooner. The bank waived the original due date and deferred repayment until receipt of the cash refunds from the Canada Revenue Agency. During the quarter ended June 30, 2009 the Company received from the Canada Revenue Agency a cash refund of \$1,016,302 excluding accrued interest, and the Company used \$730,000 of the refund to retire the credit facility.

During the year ended September 30, 2009 the Company completed a non-brokered private placement in two tranches for combined gross proceeds of \$4,664,375. The first tranche, which closed December 23, 2008, resulted in gross proceeds of \$3,000,000 through issuance of 2,400,000 common shares at \$1.25 per common share. The second tranche, which closed on January 21, 2009, resulted in gross proceeds of \$1,664,375 through the issuance of 1,331,500 shares at \$1.25 per common share. The Company paid a finder's fee in relation to the private placement satisfied through the issuance of 236,800 finder's warrants with an exercise price of \$1.90 and expiring on December 23, 2011; the issuance of 106,520 finder's warrants with an exercise price of \$1.25 and expiring on January 21, 2011; and, through the payment of \$133,150.

During the period 83,335 warrants with an expiry of April 26, 2009 were exercised resulting in the issuance of 83,335 shares and net proceeds of \$36,667 and 100,000 warrants with an expiry of April 26, 2009 were exercised resulting in the issuance of 100,000 shares and net proceeds of \$120,000. The remaining 264,838 warrants with an expiry date of April 26, 2009 expired unexercised. During the period 877,374 warrants with an expiry of April 26, 2010 were exercised resulting in the issuance of 877,374 shares and net proceeds of \$526,424. In addition, 89,147 warrants with an expiry date of December 6, 2008 and 285,404 warrants with an expiry date of June 29, 2009 expired unexercised.

Subsequent to the year ended September 30, 2009, the Company completed a private placement resulting in the issuance of 2,398,104 units for gross proceeds of \$6,594,786 (net - \$6,162,262). Each unit is 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.

## **Operational Risks**

The Company is subject to various operational risks. Factors that could cause operational 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 approval 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 sales of the Company's platforms and tests; 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 through 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.

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

Financial statements are prepared in accordance with Canadian GAAP. These accounting principles require management to make certain estimates and assumptions. Management believes that the estimates and assumptions relied upon are reasonable, based upon information available at the time that these estimates and assumptions are made. Actual results could differ from these estimates.

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 \$551,124 (September 30, 2008 - \$402,779).

### **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, 2009, 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.

## SELECTED FINANCIAL INFORMATION

The table below summarizes annual financial information for the fiscal years ending September 30, 2009 and 2008.

	Year ending September 30, 2009	Year ending September 30, 2008
Revenue	\$ 31,941	\$ 89,838
Net loss	\$ 5,909,976	\$ 3,785,579
Net loss per share	\$ (0.23)	\$ (0.18)
Weighted average shares	25,158,283	20,550,294
Total Assets	6,204,904	7,270,584

The increasing net loss trend between the year ended September 30, 2008 and the fiscal year ended September 30, 2009 primarily results from the impact of increased development spending for the scientific development of multiple autoimmune pipeline assays and the verification, validation and third party studies for the commercialization of the QuantiSpot RA and IgXplex RA test panels and SQiDworks system. Differences in the net loss for 2009 versus 2008 were also related to increased professional and consulting fees; increased stock-based compensation; expansion of infrastructure resulting in increased occupancy costs; and, amortization of property and equipment in the year ended September 30, 2009.

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 \$ 3,448,916 for the year ending September 30, 2009 compared to \$2,961,978 for the year ending September 30, 2008. The principle difference in Gross R&D expenses of \$486,938 between the two periods was:

- an expansion of development activities owing to an expanded number of autoimmune products in various stages of development in 2009 compared to 2008
- a greater level of activity and personnel additions in 2009 to complete the required work as well as resources added in late 2008 and carried into 2009;
- new expenditures for internal and third party clinical studies including increased acquisition costs for patient serum tested in these studies;
- costs related to regulatory consultants assisting the Company to plan, prepare, execute and draft regulatory filings and regulatory responses; and,

In the fiscal period ending 2009 the Company had a peak of 36 employees, 29 involved directly in R&D compared to the 2008 fiscal year when the Company had a peak of 31 employees with 28 involved directly in R&D, 5 of whom were added in the second half of the 2008 fiscal year. R&D salaries and payroll costs increased from \$2,155,513 for the period ending September 30, 2008 to \$2,371,614 for the year ending September 30, 2009. R&D consumable costs rose in proportion to the number of R&D employees, and these expenses increased by \$239,832 in the year ending September 30, 2009 above the expenses incurred in the period ending September 30, 2008.

Gross R&D expenses were offset by the recognition of Scientific Research and Experimental Development (“SRED”) cash refunds received in the 2008 fiscal year of \$929,187 resulting in net R&D expenses of \$2,032,791 and by \$87,115 in the 2009 fiscal period resulting in net R&D expenses of 3,361,81.

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, 2009 compared to the period ending September 30, 2008 from \$306,635 to \$493,015. The primary reason for the \$190,514 difference an increase in travel and related costs in fiscal 2009 related to promoting the Company’s products. Other costs related to the general growth of the corporate activities and related overheads to operate the business.

## Fourth Quarter Commentary

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

	December 31, 2008	March 31, 2009	June 30, 2009	September 30, 2009
Revenue	\$ 10,100	\$ 6,975	\$ 8,016	\$ 6,850
Net Loss	\$ 1,467,452	\$ 1,472,559	\$ 1,354,277	\$ 1,615,689
Net Loss Per Share	\$ (0.07)	\$ (0.06)	\$ (0.05)	\$ (0.06)
Weighted Average Shares	22,448,275	25,836,509	26,325,586	27,270,522

  

	December 31, 2007	March 31, 2008	June 30, 2008	September 30, 2008
Revenue	\$ 44,493	\$ 19,145	\$ 7,175	\$ 19,025
Net Loss	\$ 1,013,922	\$ 521,274	\$ 1,323,979	\$ 926,404
Net Loss Per Share	\$ (0.05)	\$ (0.03)	\$ (0.06)	\$ (0.05)
Weighted Average Shares	19,737,507	19,750,200	20,458,300	22,217,478

Revenue for the quarter ended September 30, 2009 was \$6,850 compared to \$19,025 for the quarter ended September 30, 2008. Revenue for the three month periods ending September 30, 2009 and 2008 was from service-based revenue provided to a third party.

For the quarter ended September 30, 2009, the Company recorded a net loss of \$1,615,689 (\$0.06 net loss per share) compared to a net loss of \$926,404 (\$0.05 net loss per share) for the quarter ended September 30, 2008. Per share values are based on the weighted average shares outstanding in the period. For the quarter ended September 30, 2009 there was an average of 27,270,522 shares outstanding.

Net loss and net loss per share were greater for the quarter ended September 30, 2009 compared to September 30, 2008. The increased loss for the three months ending September 30, 2009 was primarily related to ordinary increases in wage and wage-related expenses in both the Corporate and Research and Development groups, stock option expenses, consulting expenses and also in part related to the recognition of a \$283,068 cash-based SRED tax credit in the quarter ending September 30, 2008, compared to the same quarter in 2009 when no SRED credit recognition occurred; the SRED tax credit is reflected as a reduction of R&D expenses in the period it is recognized. Consulting expenses were higher in the quarter ending September 30, 2009 owing to the addition of contract resources in sales and marketing, and various operational resources not directly involved in research and development.

R&D expenditures for the three month period ended September 30, 2009 were \$872,859 and compared to the \$704,205 (before the effect of SR&ED tax credits) for the three month period ended September 30, 2008. The increase in R&D expense for the three month period ended September 30, 2009 compared to the three months ending September 30, 2008 resulted from an increase R&D activity with an increased number of assay panels in development and to regulatory validation efforts related to the SQiDworks-IgXPLEX Rheumatoid Arthritis assay system.

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 including: facility costs; insurance costs; and foreign exchange expenses. Corporate expenses totaled \$338,823 for the quarter ended September 30, 2009 compared to \$379,914 for the quarter ended September 30, 2008.

Professional consulting (legal, accounting, Board of Directors compensation, recruiting, sales and marketing, administrative contractor, and investor relations) costs in the quarter ended September 30, 2009 were \$253,609 compared to \$91,437 from the quarter ended September 30, 2008. The increase in the professional and consulting costs in the quarter ended September 30, 2009 were primarily related to consultant's fees and related travel expenses. The largest contributor to consultant's fees was the Company's addition of US-based sales and marketing resources in September 2008, and a US-based customer sales engineer was added in April, 2009 who are both engaged as consultants to the Company. During the quarter ended September 30, 2009 the Company incurred additional consulting expenses compared to the quarter ended September 30, 2008 as it utilized multiple experts in the areas of software testing, laboratory cost analysis and work-flow management, and professional recruiting costs related to growing both scientific and sales-focused expertise.

Operational expenses were partially offset by interest income earned on short-term investments and interest accrued on ITC credits outstanding. Combined, the interest income was \$121,183 and \$3,389 for the year and quarter ended September 30, 2009 respectively. The interest earned for the year and quarter ended September 30, 2008 was \$73,334 and \$26,520. The Company invests its cash in variable term cashable government investment certificates and short-term money market deposits.

Non-cash stock based compensation charges totaled \$88,610 for the quarter ended September 30, 2009 (\$379,881 - year ended September 30, 2009) compared to \$95,658 for the quarter ended September 30, 2008 (\$283,050 - year ended September 30, 2008). 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. Subsequent to the fiscal year end September 2009 the Company initiated its US sales efforts following clearance from the FDA for its SQiDworks-IgXplex RA™ system. During the 2010 fiscal year the Company plans to focus on sales and placing SQiDworks systems in US-based customers for system evaluation and expects that some of these evaluation placements will lead to commercial acceptance and revenues from sales of consumables. The Company has one such evaluation placement planned for delivery in the January 2010 at a Canadian reference laboratory.

During the fourth quarter of the 2009 fiscal year and the first quarter of the 2010 fiscal year, the Company generated significant customer feedback relating to the commercial feasibility of its system and consumable tests. Based on this market feedback, the Company believes that its strategy of focusing development, commercialization and marketing efforts on panels of autoimmune assays and targeted at medium and large reference laboratory customers continues to be sound. The Company has utilized the feedback from potential customers to validate the order and prioritization of its pipeline of products to optimize the revenue potential of the platform.

Based on its successful FDA clearance, its Health Canada licenses and EU authorization, management has increased the intensity of the development and commercialization of several new IgXplex test kits and expects this development to result in the submission of applications to the US, Canadian and EU regulatory bodies in fiscal 2010. This activity will generate increased expenses related to internal development, internal verification and validation studies and third party validation studies in the 2010 fiscal year. The Company also expects, by the end of March 2010 to offer a prototype research use only version of an anti-infliximab test kit used in the management of autoimmune disease. It is Management's expectation that the R&D expenses reported in the year ended September 30, 2009 will increase in the 2010 fiscal year. Management expects some increases to R&D salary expenses, lab expenses and validation study expenses as it increases the number of IgXplex and QuantiSpot multiplex assays that are moved from development and into third party validation studies. Each successful validation is expected to result in the filing of applications to clear these assays with the FDA and to seek regulatory approvals in Canada and the EU. It will also be necessary to invest in the administrative elements to support our customers and sales, as we place SQiDworks platforms across Canada and the United States. Management will plan to add these expenses as needed to support forecasted customer installations of SQiDworks platforms and sales of consumable kits. In general management expects an increase in administrative costs during the 2010 fiscal year. The Company's 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 will, at some point, seek additional capital to advance and accelerate the number of tests under development and being validated for regulatory submissions.

### **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, 2009 is \$50,013 (September 30, 2008 - \$33,161), related to recovery of occupancy costs, from a corporation in which an officer of the Company was also an officer. Consulting fee revenue of \$26,925 for the year ended September 30, 2009 (year ended September 30, 2008- \$89,838) was earned from this corporation. At year end, \$5,951 (September 30, 2008 - \$37,663) due from this corporation is included in amounts receivable.

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

Operational activities for the year ended September 30, 2009 were financed by cash on hand.

During the year ended September 30, 2009 the Company:

1. Increased cash reserves through the receipt of ITC credits of \$1,162,522 from outstanding prior fiscal year claims.
2. Retired a \$730,000 non-revolving credit facility;
3. Completed a non-brokered private placement in two tranches for combined gross proceeds of \$4,664,375 through the issuance of 3,731,500 shares; and,
4. Received net proceeds of \$694,841 following the exercise 1,163,211 warrants resulting in the issuance of 1,163,211 shares.

At September 30, 2009, current assets were \$3,649,024 compared to \$4,362,230 at September 30, 2008. Working capital as at September 30, 2009 was \$ 3,279,754 compared to \$3,244,418 at September 30, 2008.

Subsequent to the year ended September 30, 2009, the Company completed a private placement resulting in the issuance of 2,398,104 units for gross proceeds of \$6,594,786 (net of share issuance costs- \$6,162,262). Each unit is 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.

Management believes that cash on hand at September 30, 2009, plus cash generated subsequent to the year-end will be sufficient to fund Company operations for at least 12 months. A successful commercial launch and generation of forecasted revenue in the 2010 and 2011 fiscal years would extend this period.

## **Risks**

The Company's SQiDworks automated analytical platform and its lead QuantiSpot RA test kit used to detect and quantify a panel of biomarkers to aid in the diagnosis of rheumatoid arthritis was licensed and cleared to be sold and marketed in Canada during the quarter ended December 31, 2008 and during the quarter ended March 31, 2009 were authorized to be CE Marked and to be sold in Europe. During the quarter ended December 31, 2008, the Company filed a 510(k) Pre-market Notification with the United States Food & Drug Administration ("FDA") for review to seek approval to market and sell the IgXPLEX RA test kit and SQiDworks platform in the United States. Subsequent to the filing of the SQiDworks- IgXPLEX RA 510(k) the Company began the usual process of communication with the FDA about its filing. During the year ended September 30, 2009 the Company responded to questions from the FDA, and, subsequent to the period end, obtained clearance from the FDA for the SQiDworks- IgXPLEX RA system.

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, 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 Diagnostics' labs and at multiple third party labs, the data derived is 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 resulting in 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 and may result in shorter review periods at the FDA than was experienced with the SQiDworks- IgXPLEX RA however, 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 celiac disease, vasculitis, lupus, and Crohn's disease, are currently in the Company's discovery and development pipeline as well as a panel to detect infliximab used in the management of multiple autoimmune diseases. The anti-TNF panel is used to measure the quantity of therapeutic agent in the body and the information from this test would be used by clinicians in the management of several autoimmune diseases, including rheumatoid arthritis and IBD. The Company is expecting one, or all of these new multiplexed test panels, excepting

infliximab and the SQiDworks platform, together each a system, to be commercially ready to file applications with the applicable regulatory jurisdictions in calendar 2010.

The Company has not earned material revenues from its test kits or SQiDworks platform. The Company expects to earn revenue from its platform and IgXPLEX RA product commencing in fiscal 2010. 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 product launches of IgXPLEX RA and SQiDworks in North America and to complete development work, validation studies and regulatory efforts required for its current pipeline of up to 4 new test panels.

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, 2009, there were 27,193,024 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, 2009:

<b>Number of Warrants</b>	<b>Purchase Price</b>	<b>Expiry Date</b>
199,493	\$ 0.600	April 21, 2010
194,200	\$ 1.500	June 3, 2010
1,783,776	\$ 2.400	June 29, 2010
236,800	\$ 1.900	December 23, 2011
106,520	\$ 1.250	January 22, 2011
<b>2,520,789</b>		

The Company had the following stock options outstanding under the Plan at September 30, 2009:

<b>Number of Options</b>	<b>Exercise Price</b>	<b>Expiry Date</b>
666,680	\$ 0.600	April 15, 2010
141,670	\$ 1.200	April 15, 2010
88,891	\$ 1.200	June 29, 2011
83,335	\$ 1.200	August 29, 2011
197,500	\$ 1.740	August 7, 2012
50,000	\$ 1.500	October 23, 2012
757,500	\$ 1.600	February 15, 2013
302,500	\$ 1.750	August 26, 2013
80,000	\$ 1.300	May 21, 2014
<b>2,368,076</b>		

The Company also had 66,667 options outstanding at September 30, 2009 that were not granted under the plan. All of these options were exercisable at September 30, 2009 and have an exercise price of \$0.90 and expire on January 13, 2010. These options were all exercised subsequent to the end.

#### **Off-Balance Sheet Arrangements**

The Company has no off-balance sheet arrangements.

#### **Adoption of New Accounting Policies**

Effective October 1, 2008, the Company adopted Handbook Section 3031, which prescribes the measurement of inventories at the lower of cost and net realizable value, with guidance on the determination of cost including allocation of overheads and other costs to inventory. Reversals of previous write-downs to net realizable value are permitted when there is a subsequent increase in the value of inventories. The Company has determined that the implementation of this new standard had no impact on the Company's financial statements.

Effective October 1, 2008, the Company adopted Handbook Section 3064, Goodwill and Intangible Assets. Section 3064, which replaces Section 3062, Goodwill and Intangible Assets, and Section 3450, Research and Development Costs, establishes standards for the recognition, measurement and disclosure of goodwill and intangible assets. Adoption of this standard had no impact on the presentation of the Company's financial statements.

#### **Recent Accounting Pronouncement Issued and Not Yet Applied**

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 on its consolidated financial statements.

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 transition date of October 1, 2010 for the Company will require restatement for comparative purposes of amounts reported by the Company for the year ended September 30, 2011. While the company has begun assessing the adoption of IFRS for 2012, the financial reporting impact of the transition to IFRS has not been determined at this time.

### **Future Prospects**

In its current state of evolution, management believes that the Company has assembled the appropriate intellectual, financial, and human capital to advance its current pipeline of autoimmune test panels and SQiDworks system through the completion of clinical validation studies and regulatory filings in Canada, the U.S. and Europe. The Company believes that completion and approval, in Canada, of its lead assay and authorization to CE Mark it in Europe justifies intensified investment in development and commercialization of its pipeline of an additional group of at least nine other autoimmune microarray diagnostic panels over the next two years with four of these currently in the Company’s discovery and development process. 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 of infectious disease and allergy management. At present, the Company’s value proposition is derived from its FDA clearance, Health Canada approval and CE Marking for IgXPLEX RA and QuantiSpot RA and SQiDworks platform; the potential value in its product development pipeline; and, further future enhancements of its automated microarray processing platform. The Company’s platforms and tests are expected to replace highly manual and semi-automated test methodologies with a fully automated, multiplexed solution and to provide significant cost savings to its customers. The Company believes that the market size related to the testing of patients in its primary markets in Canada, the U.S. and Europe is significantly large and the Company’s value proposition to its customers will provide opportunities for significant revenues from the sale of commercial assays and test platforms in each of its target markets.

SQI’s operational objectives are straightforward: commercial exploitation and 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.

During the fiscal 2010 year, 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 for, celiac, vasculitis, lupus, Crohn’s and anti-infliximab products;
- 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, 2009;
- (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, 2009; 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.