

# **SQI Diagnostics Inc.**

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

**December 31, 2007**

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

*This discussion and analysis covers the unaudited financial statements for the fiscal quarters ending December 31, 2007 and December 31, 2006, prepared in accordance with Canadian generally accepted accounting principles (Canadian GAAP). Our fiscal year end 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 February 14, 2008. Certain information regarding SQI Diagnostics Inc. (or "SQI" or "Company") set forth in the 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, 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 statement will transpire or occur, or if any of them do so, what benefits that the Company will derive therefrom. Additional information relating to the Company is available by accessing the SEDAR website at [www.sedar.com](http://www.sedar.com).*

### OVERVIEW

SQI Diagnostics Inc. is a medical diagnostics systems and automation company focused on evolving laboratory-based biomarker testing. The Company is commercializing a novel and patented diagnostic platform that enables more rapid testing with significantly less effort and labour than current diagnostic technologies in the autoimmune, infectious, and allergy-related disease markets.

The Company's proprietary SQiDworks™ instrument and QuantiSpot™ consumable tests are together an immunoassay platform expected to be 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 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 participated in. The Company's first launch market will be autoimmune disease with its Rheumatoid Arthritis (RA) panel followed shortly thereafter by its Antiphospholipid Syndrome (APS).

From 2003 to present, the Company has been primarily involved in research, development and 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.

## **Commercial Development Current Status**

The Company is currently making preparations to initiate external clinical validation of its lead multiplexed test for the detection and quantification of commonly requested markers used in the diagnosis of rheumatoid arthritis. The Company has completed discussions with the United States Food and Drug Administration (FDA) to determine the final design of the validation requirements. Management intends to conduct a multi-site trial that could produce approvable data. During the current reporting period the Company shipped its SQiDworks™ platform to an external validation partner for the commencement of their initial review of the platform and preparation for performing validation studies on behalf of the Company. The Company plans to use the data from these studies in the Company's various regulatory filings to allow for the marketing and sale of the platform and QuantiSpot RA test in North America and Europe. Management expects that the external validation studies for the SQiDworks platform and QuantiSpot RA test will be concluded in the first half of calendar 2008.

## **Operational Achievements**

During the period ended December 31, 2007, the Company achieved the following steps in preparation for the intended multi-center validation studies and product commercialization:

- Platform instrument milestones were achieved including the completion of final platform configuration and assay validation protocol with agreement for use in multi-site validation study from partners;
- Our first SQiDworks™ platform was shipped to one of the Company's external validations partners, Mount Sinai Hospital in preparation for validation studies to begin in 2008;
- Lead assay configuration was locked down with performance specifications controlled for all elements of the test panel, with manufacturing parameters in place to allow for distribution to validation partners;
- Patent applications were filed in conjunction with the Company's development efforts on its Cyclic Citrullinated Peptide (CCP) marker, one of the key elements of the Company's lead RA assay. This assay has demonstrated significantly improved performance compared to other tested predicate tests and management believes that if its advanced Generation 3 CCP element is incorporated into the commercial RA test panel, the RA test could have a sustainable market advantage owing to its leading performance characteristics and proprietary technology;
- Patent applications were filed related to the SQiDworks platform further differentiating and strengthening the Company's technology position;
- Conducted initial development work on the Company's second assay for the detection and quantification of biomarkers used to aid in the diagnosis of APS. This work included proprietary manipulation of the chemistry related to the lipid capture molecules allowing them to adhere to the Company's proprietary microarray surface. Management expect this work will allow development to quickly scale up in the first half of calendar 2008 and enable the Company to complete the planned APS development activities; and,

- Successful internal quality audits were completed across the entire Company providing management with the confidence to schedule formal external audits for fiscal second quarter; these audits are required to attain our ISO 13485 certification.

### **Corporate Financing Transactions**

On April 26, 2007 umedik Inc. amalgamated with 6701914 Canada Inc., a wholly owned subsidiary of SQI to become a wholly owned subsidiary of SQI through the reverse takeover of SQI, formerly known as Emblem Capital Inc. ("Emblem"), a company whose shares were listed for trading on TSX Venture Exchange as a Capital Pool Company (CPC) just prior to the transaction. As a result of the reverse takeover umedik Inc. is a wholly owned subsidiary of SQI whose shares are listed for trading on the TSX Venture Exchange under the trading symbol SQD.

Pursuant to the Transaction, which was completed pursuant to the terms of an amalgamation agreement dated February 23, 2007 entered into between 6701914 Canada Inc., SQI and umedik Inc. (the "Amalgamation Agreement"), SQI issued 14,719,314 post-consolidation common shares in exchange for all of the issued and outstanding shares in the capital of the amalgamated company owned by the shareholders of umedik Inc. (1.6667 SQI shares issued for each share of umedik Inc.). The takeover resulted in an increase in cash of \$607,000 in umedik Inc.

The acquisition constituted Emblem's Qualifying Transaction pursuant to the rules of the TSX Venture Exchange. As a result of the share exchange, control of Emblem passed to the former shareholders of umedik Inc. Since Emblem did not constitute a business, the transaction was accounted for as a capital transaction, that is, a financing and recapitalization of umedik Inc. In addition, Emblem issued replacement options and warrants to all holders of umedik options and warrants who surrendered such securities to Emblem pursuant to the Amalgamation Agreement. The replacement options and warrants issued by Emblem are identical to the umedik options and warrants surrendered except in respect of the number of post-consolidation common shares to which a holder is entitled upon exercise and the exercise price, which terms were modified to give effect to the acquisition and share consolidation. In conjunction with the acquisition, Emblem changed its name to SQI.

On May 3, 2007, SQI received final approval from the TSX Venture Exchange for its Qualifying Transaction with umedik Inc. As a result of the completion of the Qualifying Transaction and upon receipt of final TSX Venture Exchange approval, SQI was no longer considered a Capital Pool Company. The resulting issuer, SQI, commenced trading on the TSX Venture Exchange on May 4th, 2007 under the symbol "SQD".

On May 30, 2007 an individual who had been a service provider to the Company exercised a warrant to acquire 77,501 common shares for \$0.10 per share, resulting in net proceeds to the Company of \$7,735.

On June 29, 2007 the Company completed a private placement of 3,192,551 units for net proceeds of \$4,660,435. Each unit was comprised of one common share and one-half common share purchase warrant; each unit was priced at \$1.60 per unit. Each whole warrant entitles the holder to purchase one common share for \$2.40 up to the close of business on June 29, 2009. On July 3, 2007 the Company closed the second tranche of this transaction. The net proceeds from the second tranche were \$552,000 resulting from the issuance of 375,000 units. These units were identical to the units issued in the first tranche.

On September 7, 2007 umedik Inc. changed its name to SQI Diagnostics Systems Inc.

## 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 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 lead diagnostic tests in a timely manner, if at all, and other inherent uncertainties related to the regulatory approval process;
- The Company's ability to successfully commercialize additional QuantiSpot™ tests in the autoimmune disease market;
- 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.

## SELECTED FINANCIAL INFORMATION

The table below summarizes quarterly financial information for the periods shown. For periods prior to June 2007 the information is shown for umedik Inc., on a pro rata basis. For quarters ending prior to June 30, 2007 SQI Diagnostics Inc. was a private company. In 2007 SQI Diagnostics Inc. changed its year end from December 14 to September 30.

|                         | 3 Month Periods Ending |               |                    |                   |
|-------------------------|------------------------|---------------|--------------------|-------------------|
|                         | March 31, 2007         | June 30, 2007 | September 30, 2007 | December 31, 2007 |
| Revenue                 | \$ 31,140              | \$ 22,230     | \$ 17,190          | \$ 44,493         |
| Net Loss                | \$ 838,675             | \$ 1,171,998  | \$ 946,214         | \$ 1,013,922      |
| Net Income Per Share    | \$ (0.06)              | \$ (0.07)     | \$ (0.05)          | \$ (0.05)         |
| Weighted Average Shares | 14,719,319.03          | 15,950,957    | 19,689,460         | 19,737,507        |
|                         |                        |               |                    |                   |
|                         | March 31, 2006         | June 30, 2006 | September 30, 2006 | December 31, 2006 |
| Revenue                 | \$ 82,451              | \$ 23,059     | \$ 23,400          | \$ 21,735         |
| Net Loss                | \$ 226,378             | \$ 708,376    | \$ 104,928         | \$ 712,412        |
| Net Income Per Share    | \$ (0.02)              | \$ (0.05)     | \$ (0.01)          | \$ (0.05)         |
| Weighted Average Shares | 14,719,319.03          | 14,719,319    | 14,719,319         | 14,719,319        |

## RESULTS OF OPERATIONS

For the quarter ending December 31, 2007, the Company recorded a net loss of \$1,013,922 or \$0.05 per share compared to a loss of \$946,214 or \$0.05 per share in the prior quarter ending September 30, 2007, and a loss of \$712,412 or \$0.05 per share for the quarter ending December 31, 2006. Per share values are based on the weighted average shares outstanding in the period. For the quarter ended December 31, 2007 there was an average of 19,737,507 shares outstanding. Losses were increased compared to the quarter ending December 31, 2006 owing primarily to increased development and commercialization activity on the Company's SQiDworks™ platform and its lead QuantiSpot™ autoimmune assays for the detection and quantification of biomarkers for Rheumatoid Arthritis and APS.

In the quarter ending December 31, 2007, the Company completed a Discovery Stage collaborative project to test the feasibility of developing an infectious disease assay to detect the presence and levels of antibodies used to diagnose infection with Botulism organisms. Upon successful completion of a demonstration microarray of three multiplexed biomarkers the Company's development partner, Silliker Inc. paid the Company milestone payment related to the Discovery Phase work that was responsible for the increase in revenue compared to both the previous and the quarter ending December 31, 2006. Revenue for the quarter ending December, 2007 was \$44,493 compared to \$21,735 in the quarter ending December 31, 2006.

Research and development expenses include R&D salaries, benefits, all laboratory costs and R&D related professional services and contracts. These expenses totaled \$698,660 for the quarter ending December 31, 2007 and were \$380,293 for the quarter ending December 31, 2006. The increased R&D costs for the quarter ending December 31, 2007 compared to quarter ending December 31, 2006 were primarily related to increased staffing and activities required for the development and commercialization of the automated platform and two lead assays. The greatest contributor to the increase in R&D expense in the quarter ending December 31, 2007 compared to the same period last year was the increase in R&D salary and benefit expenses owing to the hiring of eleven new R&D employees in 2007. The staff additions made in 2007 are currently involved in a variety of R&D-focused efforts including basic science, platform engineering and software development, regulatory, laboratory quality assurance and novel manufacturing projects.

General and administrative 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; facility costs; professional fees; insurance costs; and foreign exchange expenses. General and administrative expenses totaled \$221,487 for the quarter ending December 31, 2007 compared to \$251,184 quarter ending December 31, 2006. General and administrative expenses were lower in the quarter ending December 31, 2007 compared to the same period in the previous year owing to a reduction of corporate salary expense following the reduction in staffing by two employees.

Operational expenses were partially offset by interest income earned on short term investments of \$11,961 for the quarter ending December 31, 2007 compared to \$21,710 for the quarter ending December 31, 2006. The decrease in interest income from quarter ending December 31, 2007 compared to the quarter ending December 31, 2006 relates primarily to lower market rates available for investment of the Company's cash. The Company invests its cash in variable term cashable government investment certificates.

Non-cash stock based compensation charges totaled \$35,462 for the quarter ending December 31, 2007 compared to \$55,091 for the quarter ending December 31, 2006. The related stock option issuances are described further below in the Outstanding Share Capital section.

Management expects losses to continue for at least the next fiscal year as investment continues in product research, development, and commercialization efforts, including third party validation trials and regulatory compliance. These losses are expected to increase moderately in 2008 compared to similar periods in 2007, with the anticipated launch of the Company's first product and the expected commercialization of several additional products in 2008.

## LIQUIDITY AND CAPITAL RESOURCES

### Sources and Uses of Cash

Operational activities for the period ended December 31, 2007 were financed by cash on hand and by the proceeds of a private placement that closed on June 29, and July 3, 2007, yielding gross proceeds of \$5.7 million through the issuance of 3,567,551 units consisting of one common share and one-half common share purchase warrant. At December 31, 2007, current assets were \$2,756,674 as compared to \$3,674,792 at September 30, 2007. Working capital as at December 31, 2007 was \$2,240,860. Management believes that with the cash on hand at December 31, 2007, with no significant capital investments and with no increases in to its current operating expenditures, the current financial resources would be sufficient to fund Company operations through 2008.

As at December 31, 2007, and in the normal course of business, the Company is obligated to make future payments.

These obligations represent contracts and other commitments that are known and committed.

|                         | 2008     | 2009    | 2010    |
|-------------------------|----------|---------|---------|
| <b>Equipment Leases</b> | \$11,337 | \$7,866 | \$7,866 |
| <b>Facilities Rent</b>  | \$58,032 |         |         |
|                         | \$69,369 | \$7,866 | \$7,866 |

### Financial Instruments and Financing Risks

While the Company currently does not market any diagnostic tests or platforms, its 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, and QuantiSpot™ APS, a diagnostics test kit used to detect and quantify a panel of biomarkers to aid in the diagnosis of APS, are being prepared for third party clinical validation studies. QuantiSpot™ tests are designed to run only on the SQiDworks™ platform. In order to get the platform and QuantiSpot™ consumable tests approved for sale in the United States, the Food & Drug Administration ("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 the validation studies 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 four months to render a decision on the application. The Company has completed extensive internal testing of its QuantiSpot™ RA test panel using the SQiDworks™ platform and has completed extensive development testing of its QuantiSpot™ APS test panel.

The Company has not earned revenues from its QuantiSpot™ test kits or SQiDworks™ platform and is therefore considered to still be in the development stage. The continuation of the Company's research and development activities is dependent upon the Company's ability to

successfully finance its cash requirements through the generation of revenue from its partners and potential customers, or to complete further equity financing. Management believes that it has sufficient cash reserves to complete validation studies related to its lead RA test and to await the expected response on its 510(k) pre-market notification from the FDA.

Management will continue to review the Company's financial needs through 2008 and to seek additional capital financing as required from sources that may include equity 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 December 31, 2007, there were 19,750,200 common shares issued and outstanding. In addition, the following securities have been issued that are convertible under certain conditions into common shares:

The Company had the following warrants outstanding at December 31, 2007:

| <b>Number of Warrants</b> | <b>Purchase Price</b> | <b>Expiry Date</b> |
|---------------------------|-----------------------|--------------------|
| 83,335                    | \$ 0.438              | April 26, 2009     |
| 50,001                    | \$ 0.132              | April 26, 2009     |
| 20,834                    | \$ 1.200              | April 26, 2009     |
| 89,147                    | \$ 2.502              | April 26, 2009     |
| 1,076,867                 | \$ 0.600              | April 26, 2009     |
| 344,004                   | \$ 1.200              | April 26, 2009     |
| 285,404                   | \$ 1.600              | June 29, 2009      |
| 1,783,776                 | \$ 2.400              | June 29, 2009      |
| <b>3,733,368</b>          |                       |                    |

The Company had the following stock options outstanding under its Employee Stock Option Plan at December 31, 2007:

| <b>Number of Options</b> | <b>Exercise Price</b> | <b>Expiry Date</b> |
|--------------------------|-----------------------|--------------------|
| 133,336                  | \$ 0.132              | December 16, 2008  |
| 8,334                    | \$ 1.680              | July 1, 2009       |
| 141,670                  | \$ 1.200              | April 15, 2010     |
| 283,339                  | \$ 1.200              | June 29, 2011      |
| 166,670                  | \$ 1.200              | August 29, 2011    |
| 197,500                  | \$ 1.740              | August 7, 2012     |
| 50,000                   | \$ 1.500              | October 23, 2012   |
| <b>980,849</b>           |                       |                    |

The Company also had 966,683 options outstanding at December 31, 2007 that were not issued under the plan. All of these options were exercisable at December 31, 2007. 133,333 options have an exercise price of \$0.90 and expire on October 14, 2009 and 833,350 options have an exercise price of \$0.60, expiring on April 15, 2010.

### 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 appropriate intellectual, financial, and human capital to advance its lead test microarray panels and SQiDworks™ automated instrument for the detection and quantification of antibodies linked to the diagnosis of rheumatoid arthritis, APS and other autoimmune diseases through the completion of clinical validation studies and regulatory filings in Canada, the US and Europe. The Company believes that completion and approval of its lead assay will justify the investment in development and commercialization of an additional group of at least eight other autoimmune microarray diagnostic panels in the autoimmune disease family. It further believes that successful completion of these tests will 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. The successful completion of external validation studies has the potential to produce data by the end of the second calendar quarter of 2008 that is presentable to the FDA in the form of a Pre Market Submission - 510(k), which can result in marketing approval for the Company's platform and lead assays in the United States. At present, the Company's value proposition is derived from the successful completion of internal validation studies and completion of its automated microarray processing platform. The Company's platform and tests are expected to replace highly manual and semi-automated test methodologies with a fully automated, multiplexed solution that could provide significant cost savings to its customers. The Company believes that the market size related to testing of patients in its primary markets in Canada, the US and Europe is significantly large and the Company's value proposition to its customers will provide for significant revenues from the sale of commercial assays and test platforms in each of its target markets.

SQI's operational objectives are straightforward: complete external validation of its lead multiplexed test for rheumatoid arthritis on the SQiDworks platform; submit approvable data to the FDA, HPB (Canada); and, self-certify for marketing in Europe with a CE mark for a Class II device. Success in these steps will allow the Company to validate its multiplexing model and sell its products to customers in its target markets by the end of 2008.

During 2008, the Company plans to execute on the following components of its operational strategy:

- Execute clinical validation trials with its leading autoimmune disease testing partners at Mount Sinai Hospital (Toronto, Ontario) and The Cleveland Clinic (Cleveland, Ohio);
- Complete the certification of its cGMP/ISO 13485 manufacturing facility and acquire appropriate regulatory approvals and licenses to produce saleable products;
- Submit all requested information to the FDA and Health Canada, including updated manufacturing data and finalized submissions for 510(k) clearance for the Company's rheumatoid arthritis detection and quantification panel and when successful follow on with the required submissions for approval for our APS product;
- Initiate development and commercialization of IBS (Irritable Bowel Syndrome) related multiplexed test panels; and,
- Acquire customers to generate first test kit based revenues.

The Company continues 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. 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 December 31, 2007;
- (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 December 31, 2007; 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.