

# Winning the Battle Against Sepsis



Dear Shareholders,

Enrollment in our EUPHRATES trial in the second quarter progressed at an accelerated rate compared to the same period last year.

Directed by the Company's Endotoxin Activity Assay (EAA™), which is the only FDA-cleared diagnostic for the risk of developing sepsis, Spectral's EUPHRATES trial is targeted to enroll 306 evaluable patients.

Subject to maintaining current enrollment rates and timely site start ups, the trial should be fully enrolled in the second half of 2014. As of August 12, 2013, 159 patients have been randomized into Spectral's EUPHRATES trial.

The progress with the trial's patient enrollment moves us closer to the study's planned, second interim analysis. We are optimistic that the results from the second interim analysis should support the successful completion of the trial.

At the second interim analysis, the Data and Safety Monitoring Board will advise Spectral on the trial's safety, efficacy or futility, with stopping rules in place for efficacy and futility. A sample size recalculation will be done if necessary. Management intends to disclose the results of the interim analysis after 184 patients have been randomized and followed for 28 days, and the data from the analysis has been thoroughly reviewed.

We remain on track to disclose information from the second interim analysis in late 2013 or early 2014.

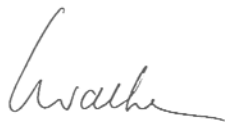
Subsequent to quarter end, we disclosed that the trial's composite 28-day mortality rate was approximately 33 per cent for randomized patients. The composite mortality rate continues to suggest that we are enrolling patients who are most likely to benefit from Spectral's treatment.

Also during the quarter, we announced the appointment of Dr. Gualtiero Guadagni as the Company's Vice President, Sales and Marketing. Dr. Guadagni will primarily be responsible for the development and expansion of commercial opportunities for Toraymyxin and Spectral's Endotoxin Activity Assay in Canada, the United States and Europe.

Looking ahead, we are very optimistic about Spectral's future. Positive trial results for our theranostic could lead to approval for commercialization by the U.S. FDA. If our theranostic is cleared for sale in the U.S., we can potentially help patients who are sick or dying from septic shock.

I would like to thank our shareholders for your continuing support and I look forward to updating you on the progress of the EUPHRATES trial.

Sincerely,



Dr. Paul Walker  
President & CEO

## **MANAGEMENT'S DISCUSSION & ANALYSIS**

**(All figures are expressed in thousands of Canadian dollars)**

This Management's Discussion & Analysis ("MD&A") for the six months ended June 30, 2013 has been prepared to help investors understand the financial performance of the Company in the broader context of the Company's strategic direction, the risks and opportunities as understood by management, and the key success factors that are relevant to the Company's performance. Management has prepared this document in conjunction with its broader responsibilities for the accuracy and reliability of the financial statements, as well as the development and maintenance of appropriate information systems and internal controls to ensure that the financial information is complete and reliable. The Finance and Audit Committee of the Board of Directors has reviewed this document and all other publicly reported financial information for integrity, usefulness, reliability and consistency.

This discussion should be read in conjunction with the Condensed Interim Financial Statements of the Company, and the notes thereto, for the six months ended June 30, 2013 (the "Condensed Interim Financial Statements") and the Audited Annual Financial Statements of the Company, and the notes thereto for the years ended December 31, 2012 and 2011 (the "Annual Financial Statements"), as well as management's discussion and analysis for the year ended December 31, 2012.

### **FORWARD LOOKING STATEMENTS**

Certain statements contained in this MD&A constitute forward-looking information within the meaning of securities laws. Forward-looking information may relate to our future outlook and anticipated events or results and may include statements regarding our future financial position, business strategy, budgets, litigation, projected costs, capital expenditures, financial results, taxes and plans and objectives. In some cases, forward-looking information can be identified by terms such as "may", "will", "should", "expect", "plan", "anticipate", "believe", "intend", "estimate", "predict", "potential", "continue" or other similar expressions concerning matters that are not historical facts. These statements are based on certain factors and assumptions regarding, among other things, expected growth, results of operations, performance, and business prospects and opportunities. While we consider these assumptions to be reasonable based on information currently available to us, they may prove to be incorrect. Forward looking-information is also subject to certain factors, including risks and uncertainties that could cause actual results to differ materially from what we currently expect. These factors include, among other things, the availability of funds and resources to pursue development projects, the successful and timely completion of clinical studies and regulatory filings, the ability to take advantage of business opportunities, the granting of necessary approvals by regulatory authorities, the ability to manufacture our products, and general economic, market and business conditions. For more exhaustive information on these risks and uncertainties you should refer to our most recently filed Annual Information Form which is available at [www.sedar.com](http://www.sedar.com). Forward-looking information contained in this MD&A is based on our current estimates, expectations and projections, which we believe are reasonable as of the current date. You should not place undue importance on forward-looking information and should not rely upon this information as of any other date. While we may elect to, we are under no obligation and do not undertake to update this information at any particular time.

### **DISCLOSURE CONTROLS AND INTERNAL CONTROLS**

The Company's management maintains a system of disclosure controls and procedures to provide reasonable assurance that material information is made known, and has designed internal controls over financial reporting to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with Canadian generally accepted accounting principles ("Canadian GAAP"), defined as International Financial Reporting standards ("IFRS") as set out in the Handbook of the Canadian Institute of Chartered Accountants applicable to the preparation of interim financial statements, including IAS 34 "Interim Financial Reporting". There has been no change during the Company's most recent interim period in the internal controls over financial reporting.

The accounting policies applied in these Condensed Interim Financial Statements are based on IFRS effective for the six months ended June 30, 2013, as issued and outstanding as of August 12, 2013, the date the Board of Directors approved the statements. Any subsequent changes to IFRS that are given effect in the Company's Condensed Interim Financial Statements for the six months ended June 30, 2013 could result in restatement of these financial statements, including the transition adjustments recognized on the change-over to IFRS.

Dr. Paul M. Walker, Chief Executive Officer, and Mr. Anthony Businkas, Chief Financial Officer, in accordance with Multilateral Instrument NI 52-109, have also both certified that:

- They have reviewed the Condensed Interim Financial Statements and this MD&A ("the Filings");
- Based on their knowledge, these Filings do not contain any untrue fact or omit a material fact;
- The Filings present fairly the financial position, loss and comprehensive loss, and cash flows of the Company;
- They have designed such disclosure controls and procedures, or caused them to be designed under their supervision, to provide reasonable assurance that material information relating to the Company is made known to them by others within the Company, particularly during the period in which the annual filings are being prepared;
- They have designed such internal controls over financial reporting, or caused them to be designed under their supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with IFRS.

This document and the related financial statements can also be viewed on the Company's website at [www.spectraldx.com](http://www.spectraldx.com) and at [www.sedar.com](http://www.sedar.com). The Company's Annual Information Form and Management Information Circular are also available on these websites.

## INTRODUCTION

Spectral Diagnostics Inc. (“Spectral” or the “Company”) is strategically focused on the development and commercialization of a treatment for severe sepsis and septic shock utilizing its Endotoxin Activity Assay (EAA™) and the Toraymyxin therapeutic. If approved, this will be the first theranostics product, a targeted therapy guided by a specific diagnostic, in the area of sepsis. The Company also manufactures and sells certain proprietary reagents.

### EAA™

Spectral has pioneered the development of biochemical markers for the clinical syndrome known as “severe sepsis”. In 2003, the Company achieved U.S. Food and Drug Administration (“FDA”), Health Canada and European CE clearance of the Endotoxin Activity Assay (“EAA™”) for the first recognized rapid test for the risk of developing sepsis in the Intensive Care Unit (“ICU”). In North America alone over 1,000,000\* patients are diagnosed with the clinical syndrome of sepsis annually. Between 30% and 50% of patients with severe sepsis die in the ICU. Earlier identification and treatment of patients at risk for sepsis reduces mortality and saves significant costs by reducing the length of stay in the ICU and helping to guide therapeutic interventions. Spectral’s EAA™ endotoxin measurement is the only FDA cleared diagnostic for this indication currently on the market.

### TORAYMYXIN

Toraymyxin is a therapeutic hemoperfusion device that removes endotoxin from the bloodstream. Toraymyxin has been used in more than 100,000 patients globally and has demonstrated in clinical trials that it safely and effectively removes endotoxin and reduces mortality in patients with severe sepsis.

Results of a randomized controlled trial (the EUPHAS trial) were published in the *Journal of the American Medical Association* (JAMA, 2009; Vol. 301 No. 23, 2445-2452). The results demonstrated that when Toraymyxin is added to conventional therapy, there is significantly improved hemodynamics and organ function, and reduced 28-day mortality in patients with severe sepsis and septic shock in comparison to those patients in the conventional therapy group.

### PROPRIETARY REAGENTS

Spectral develops, produces and markets recombinant proteins, antibodies and calibrators. These materials are sold for use in research and development as well as in products manufactured by other diagnostic companies through non-exclusive license and supply agreements. Royalty revenues are earned from these license arrangements based on a percentage of end user sales of Troponin I.

## CLINICAL DEVELOPMENT

The Company’s current clinical development program is focused on obtaining U.S. FDA approval for Toraymyxin.

On March 6, 2009, Spectral signed a license agreement with Toray Industries, Inc. of Japan granting Spectral the exclusive development and commercial rights in the U.S. for Toraymyxin, a therapeutic device for the treatment of sepsis that removes endotoxin from the bloodstream. Under the terms of the agreement, Spectral is seeking U.S. FDA approval for Toraymyxin and intends to commercialize the product, together with its Endotoxin Activity Assay (EAA™), the only FDA cleared diagnostic for the measurement of endotoxin.

On February 26, 2010, the Company received final approval of its Investigation Device Exemption (“IDE”) from the U.S. FDA, which permits the Company to conduct a pivotal trial for Toraymyxin (the EUPHRATES trial) in the United States.

\* Ref: Martin. G., *Expert Rev Anti Infect Ther.* 2012 June; 10(6): 701-706

On March 2, 2010, the Company completed a private placement financing for aggregate gross proceeds of \$19,500. Net proceeds from the financing, after related costs, were \$17,608. These funds have been utilized primarily for the regulatory approval of Toraymyxin in the U.S. market.

In October, 2010, the Company announced the initiation of its EUPHRATES trial (Evaluating the Use of Polymyxin B Hemoperfusion in a Randomized controlled trial of adults Treated for Endotoxemia and Septic shock) in the United States comparing standard of care versus Toraymyxin plus standard of care. The trial, as currently configured, is expected to enroll 306 evaluable patients and has a primary end point of 28 day mortality.

In November, 2010, the Company signed a long-term, exclusive distribution agreement with Toray Industries, Inc. and Toray Medical Co., Ltd. of Japan (collectively "Toray") to market and sell Toraymyxin in Canada. Both the Toraymyxin product and Spectral's EAA™ diagnostic are already approved for sale by Health Canada. The Company is developing commercial plans for the Canadian market. The first step in the Canadian commercialization process is the inclusion of Canadian sites in the EUPHRATES trial.

On September 9, 2011, the Company completed a plan of arrangement with Medwell Capital Corp. ("Medwell"), whereby Spectral issued 33,333,333 common shares in exchange for \$10 million cash. In accordance with the plan of arrangement, Medwell distributed 54,282,834 Spectral common shares to its shareholders and retained a 13.40% residual ownership position in Spectral. These funds are being utilized primarily for the execution and expansion of the EUPHRATES trial.

In the fourth quarter of 2011, "Xigris", an Eli Lilly product, was withdrawn from the worldwide market, following results of a European clinical study which showed that the trial did not meet the primary endpoint of a statistically significant reduction in 28-day all cause mortality in patients with septic shock. In February, 2012, the first of two anticipated pivotal phase III sepsis studies for Tolactoferrin alfa ("Aggenix AG") was halted for safety reasons. While unfortunate for sepsis patients and clinicians, the opportunity to find an effective treatment remains.

On June 20, 2012, the FDA approved the Company's request to add up to an additional 30 clinical trial sites. The Company now has the capability to expand the trial to a total of 60 clinical sites in North America and internationally. There are currently 40 operational sites, of which 5 have enlisted an additional institution, bringing the total number of operational hospitals to 45. The Company has targeted up to 45 sites to be enrolling patients by the end of the third quarter and anticipates that no more than 50 sites will ultimately be activated for the trial.

On September 26, 2012, the FDA approved an amended protocol for the EUPHRATES trial, which provides for two planned interim analyses instead of one.

In January, 2013 the first interim analysis was conducted on the 76 randomized patients who were followed for 28 days. The Data Safety and Monitoring Board ("DSMB"), consisting of experts in the fields of critical care medicine, infectious disease, nephrology, biostatistics and regulatory affairs, reviewed the totality of the data set for evidence of safety concerns, such as adverse events and/or adverse device effects, related to the use of the Toraymyxin cartridge. The results from the first interim safety analysis by the DSMB stated that there are no safety issues to date concerning the application of the Toraymyxin cartridge to patients in the EUPHRATES trial. In addition, the results stated that the EUPHRATES clinical protocol appears to be defining the correct target patient population for this study.

The results of the second interim analysis (184 randomized patients followed for 28 days) are expected to be known by the end of 2013, or early 2014.

At the second interim analysis, the Data Safety Monitoring Board will advise the Company on the trial's safety, efficacy or futility, with stopping rules in place for efficacy and futility. A sample size recalculation will be done if necessary.

On May 1, 2013 the Company announced the appointment of Dr. Gualtiero Guadagni as the Company's Vice President, Sales and Marketing. Dr. Guadagni will primarily be responsible for the development of sales and marketing programs, the expansion of commercial opportunities and the execution of sales and marketing initiatives for Toraymyxin and the Company's Endotoxin Activity Assay (EAA™) in Canada, the United States and Europe.

As of August 12, 2013 a total of 159 patients had been randomized into the trial after meeting both clinical entry criteria and the biomarker criteria of a high endotoxin level. The EUPHRATES trial's enrollment rate continues to exceed, on a per-site basis, enrollment rates of previous sepsis trials. The number of enrolled patients has now exceeded the half-way mark of the trial which, as currently configured, is expected to enroll 306 evaluable patients by the end of 2014.

The EUPHRATES trial is the only active and most innovative Phase III study in the area of septic shock.

At June 30, 2013, the Company had approximately \$10,600 of cash, cash equivalents and a short-term investment to fund its clinical development activities and operations

Toraymyxin is marketed in Japan and Europe and has been used to treat more than 100,000 sepsis patients safely and effectively. Spectral's EAA™ can identify patients that will benefit from Toraymyxin and monitor the effects of the treatment. This combination of the EAA™ diagnostic and the Toraymyxin therapeutic has been utilized by clinicians in Europe since November 2007 and has demonstrated a significant reduction in mortality. The market opportunity for Spectral is large, as the combined diagnostic and therapeutic product is expected to fulfill a major unmet need for the approximately 350,000 patients who develop severe sepsis or septic shock in the U.S. each year. Over half of these patients have highly elevated levels of endotoxin. The U.S. market potential for this treatment is estimated at over \$ 1 billion.

## **OPERATIONS**

During the first six months of 2013, the Company's activities continued to focus on execution of the EUPHRATES trial.

The Company also continued to sell its EAA™ diagnostic and its proprietary reagents under the terms of existing commercial arrangements.

## **OPERATING RESULTS**

### **SELECTED FINANCIAL INFORMATION**

#### **REVENUE**

Revenue for the three months ended June 30, 2013 was \$572, compared to \$599 for the same period in the preceding year. For the six months ended June 30, 2013 revenue was \$1,280 compared to \$1,275 for the same period in 2012.

It is anticipated that revenue in 2013 will remain consistent with levels achieved in 2012. The Company expects to expand its distribution network for the EAA™ diagnostic over the last half of the year with anticipated incremental revenues starting in 2014.

#### **EXPENSES**

Total expenses for the three months ended June 30, 2013 were \$3,642, compared to \$2,798 in the second quarter of 2012. For the six months ended June 30, 2013 total expenses were \$6,449 compared to \$5,774 for the same period in 2012. This net increase of \$675 for the six months ended June 30, 2013 is primarily attributable to the higher EUPHRATES costs of \$1,261, offset by the \$475 decrease in management services fees and lower investor relations program costs.

The Company continues to maintain a low cost operating structure for its current business and expects no material increase in non clinical operating costs in 2013.

EUPHRATES trial costs (as disclosed in Note 9 of the Condensed Interim Financial Statements) were \$3,830 in the first six months of 2013, compared to \$2,569 for the same period in 2012. This increase of \$1,261 is primarily due to the initiation of additional sites, the increased number of enrolled patients, and costs associated with the third investigator meeting held in April, 2013.

The \$175 of management services was paid to Medwell for the provision of various consulting services. The Company entered into a services agreement with Medwell effective January 1, 2010, which agreement was later amended on January 1, 2011. Under the terms of the agreement Medwell was paid \$1,500 per annum, plus applicable expenses from January 1, 2011 through July 31, 2012. Effective August 1, 2012, pursuant to a restructuring of the services agreement, Medwell was paid \$400 per annum plus up to \$50 of applicable expenses to December 31, 2013. The Company provided notice of termination effective May 14, 2013. A termination fee of \$125 was paid on that date, representing 50% of the remaining amounts due under the contract to December 31, 2013.

Finance income represents interest earned on Company's short-term investment.

## PRIVATE PLACEMENT

On April 2, 2013, the Company completed a private placement financing, whereby the Company issued 18,666,667 common shares in the capital of the Company ("Common Shares"), at a price of \$0.30 per Common Share, to three investors for aggregate gross proceeds of \$5,600 ("the Private Placement"). The Company received net proceeds of \$5,455 which will be used to continue to support the Company's EUPHRATES clinical trial and for general corporate purposes. As part of the Private Placement, Toray Industries, Inc. ("Toray") acquired 16,666,667 Common Shares at a price of \$0.30 per Common Share, for \$5,000, representing approximately 12.6% of the issued and outstanding Common Shares, calculated on a non-diluted basis.

## BALANCE SHEET, FINANCIAL CONDITION AND LIQUIDITY

Cash, cash equivalents and short-term investment of \$10,648 as at June 30, 2013 (December 31, 2012 - \$10,562) increased by \$86. This increase is attributable to the following cash utilization:

Cash operating losses	(4,897)
Private placement	5,455
Working capital	(236)
Property, plant and equipment additions	<u>(236)</u>
	<u>\$86</u>

## OUTLOOK

The Company will continue to generate sales in 2013 pursuant to its existing commercial arrangements for EAA™ and its proprietary biological reagents. The strategic focus continues to be on the successful implementation and completion of the EUPHRATES trial.

At this time, it is anticipated that the Company will reach the cumulative 184 randomized patients required for its second interim analysis in the fourth quarter of 2013 and release the results of the analysis by early



2014. Completion of total patient enrolment for the trial (306 evaluable patients as currently configured) is targeted for the end of 2014.

As at June 30, 2013 the Company had \$10,648 available to fund its clinical and market development activities and its operations. We will continue to monitor our funding needs to successfully complete the EUPHRATES trial and to execute market development initiatives for our products. The amount of any additional funds required for our clinical and product development programs is dependent in part on the interim results, which will help determine whether the trial should continue as currently configured, or whether we will need to add to the clinical program. The Company intends to raise additional funds as necessary.

## **BUSINESS RISKS**

The Company's operations are exposed to a variety of risk factors inherent in new product development. The Company's short operating history in its new endeavours makes prediction of future operating results difficult. Actual future results may differ significantly from those projected in any forward-looking statements. Key business risks for the Company are detailed in its most recent Annual Information Form which is available at [www.sedar.com](http://www.sedar.com).

## **CRITICAL ACCOUNTING POLICIES**

The Condensed Interim Financial Statements of Spectral for the six months ended June 30, 2013 are prepared in accordance with IAS 34, "Interim Financial Reporting". The Condensed Interim Financial Statements should be read in conjunction with the Annual Financial Statements for the year ended December 31, 2012, which have been prepared in accordance with IFRS. The Company has identified the accounting policies and estimates that are critical to the understanding of the Company's operation and financial results in the Condensed Interim Financial Statements. Certain policies are selected by management and approved by the Finance and Audit Committee of the Board of Directors. These accounting policies are set out in Note 3 of the Annual Financial Statements for the years ended December 31, 2012 and 2011. Certain policies are more significant than others and are, therefore, considered critical accounting policies. Accounting policies are considered to be critical if they rely on a substantial amount of judgment in their application or if they result from a choice between accounting alternatives and that choice has a material impact on the reported results or financial position.

In addition to accounting policies, management is required to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the Condensed Interim Financial Statements and the reported amounts of revenue and expenses during the reporting period. The most significant estimates are related to the recoverability of purchased technology and licences, property, plant and equipment and valuation assumptions related to share-based compensation. Actual results could differ from those estimates. The Condensed Interim Financial Statements of the Company have been prepared using similar estimation methods for the critical accounting estimates as were used for the Annual Financial statements and they conform to the requirement of IAS 34 "Interim Financial Reporting".

## **RISK MANAGEMENT**

### **FINANCIAL RISK MANAGEMENT**

In the normal course of business, the Company is exposed to a number of financial risks that can affect its operating performance. These risks are: market risk (including currency risk, fair value interest rate risk, cash flow interest rate risk and price risk), credit risk and liquidity risk. The Company's overall risk management program and prudent business practices seek to minimize any potential adverse effects on the Company's financial performance.

#### **a. Market Risk**

- i. Currency risk: The majority of the Company's revenue is denominated in U.S. dollars and Euros. At June 30, 2013, cash included US\$74. Trade and other receivables included a total of US\$376 and €55. Trade and other liabilities included a total of US\$1,266 and €1. There is no active hedging program currently in place due to the relatively short time frame for settlement of these balances. A 10% change in the US/CDN or EURO/CDN exchange rate on the June 30, 2013 amounts would have a \$79 impact on net income.
- ii. Interest rate risk: The Company has no material exposure to fluctuations in interest rates.

#### **b. Credit Risk**

- i. Cash: The Company places its cash with Canadian Schedule I banks.
- ii. Cash equivalent: Cash equivalent consist of a premium money market investment account placed with a Canadian Schedule I bank. The premium money market investment account can be converted to cash on demand.
- iii. Short-term investment: Short-term investment includes an interest bearing security with an original maturity of greater than three months and remaining maturity of less than one year. The short-term investment is classified as held-for-trading and is accounted for at fair value.
- iv. Accounts receivable: The Company sells its products to distribution partners in major markets. The credit risk associated with the accounts receivable pursuant to these agreements is evaluated during initial negotiations and on an ongoing basis. There have been no events of default under these agreements. As at June 30, 2013 and 2012, no material accounts receivable balances were considered impaired or past due.

#### **c. Liquidity Risk**

There has been no material change since the Company's year end.

#### **CAPITAL RISK MANAGEMENT**

The Company's primary objective, when managing capital, is to maintain appropriate levels of cash and cash equivalents for working capital and operating purposes, as well as funding commercialization of its core products. Capital includes shareholders' equity.

# Spectral Diagnostics Inc.

Condensed Interim Financial Statements

**June 30, 2013**  
(Unaudited)

These unaudited condensed interim financial statements have been prepared by management of Spectral Diagnostics Inc. and have not been reviewed by the Company's auditor.

# Spectral Diagnostics Inc.

## Condensed Interim Statement of Financial Position

(in thousands of Canadian dollars)

	Note	June 30 2013 \$	December 31 2012 \$
		Unaudited	Audited
<b>Assets</b>			
<b>Current assets</b>			
Cash and cash equivalents		5,459	5,425
Short-term investment		5,189	5,137
Trade and other receivables		563	590
Inventories		418	277
Prepayments		311	226
		11,940	11,655
<b>Non-current assets</b>			
Property, plant and equipment		631	497
Intangible assets		422	434
		1,053	931
<b>Total assets</b>		<b>12,993</b>	<b>12,586</b>
<b>Liabilities</b>			
<b>Current liabilities</b>			
Trade and other payables		1,925	1,913
Deferred revenue		50	99
<b>Total liabilities</b>		<b>1,975</b>	<b>2,012</b>
<b>Equity</b>			
Share capital	12	32,556	27,101
Contributed surplus		3,864	3,864
Other equity reserves	8	8,366	8,260
Deficit		(33,768)	(28,651)
<b>Total equity</b>		<b>11,018</b>	<b>10,574</b>
<b>Total liabilities and equity</b>		<b>12,993</b>	<b>12,586</b>

The accompanying notes are an integral part of these unaudited condensed interim financial statements.

# Spectral Diagnostics Inc.

Condensed Interim Statement of Loss and Comprehensive Loss

For the six months ended June, 2013 and 2012

(Unaudited)

(in thousands of Canadian dollars, except for share and per share data)

	Note	Three months ended June 30		Six months ended June 30	
		2013 \$	2012 \$	2013 \$	2012 \$
<b>Revenue</b>		572	599	1,280	1,275
Other income		14	30	19	66
<b>Expenses</b>					
Changes in inventories of finished goods and work- in-process		38	52	121	151
Raw materials and consumables used		170	103	281	202
Employee benefits	8, 10	714	641	1,454	1,406
Consulting and professional fees		1,874	1,056	3,178	2,246
Management services	11	175	375	275	750
Regulatory and investor relations		58	99	106	222
Travel and entertainment		451	313	670	459
Depreciation and amortization		59	55	114	106
Foreign exchange (gain)loss		(9)	(7)	-	4
Other expenses		112	111	250	228
		3,642	2,798	6,449	5,774
<b>Operating loss</b>		(3,056)	(2,169)	(5,150)	(4,433)
Finance income		16	18	33	34
<b>Loss and comprehensive loss for the period</b>		(3,040)	(2,151)	(5,117)	(4,399)
<b>Basic and diluted loss per common share</b>		(0.02)	(0.02)	(0.04)	(0.04)
<b>Weighted average number of common shares outstanding</b>		132,139,805	113,883,394	123,062,031	113,883,394

The accompanying notes are an integral part of these unaudited condensed interim financial statements.

## Spectral Diagnostics Inc.

### Condensed Interim Statement of Changes in Equity (Unaudited)

(in thousands of Canadian dollars, except number of shares)

	Note	Issued capital Number	\$	Contributed surplus \$	Share-based compensation \$	Warrants \$	Deficit \$	Total equity \$
<b>Balance, January 1, 2012</b>		113,883,394	27,101	3,864	2,939	5,143	(20,108)	18,939
Loss and comprehensive loss for the period		-	-	-	-	-	(4,399)	(4,399)
Share-based compensation	8, 10	-	-	-	123	-	-	123
<b>Balance, June 30, 2012</b>		113,883,394	27,101	3,864	3,062	5,143	(24,507)	14,663
<b>Balance, January 1, 2013</b>		113,883,394	27,101	3,864	3,117	5,143	(28,651)	10,574
Loss and comprehensive loss for the period		-	-	-	-	-	(5,117)	(5,117)
Private placement	12	18,666,667	5,455	-	-	-	-	5,455
Share-based compensation	8, 10	-	-	-	106	-	-	106
<b>Balance, June 30, 2013</b>		132,550,061	32,556	3,864	3,223	5,143	(33,768)	11,018

The accompanying notes are an integral part of these unaudited condensed interim financial statements.

# Spectral Diagnostics Inc.

Condensed Interim Statement of Cash Flows  
For the six months ended June 30, 2013 and 2012  
(Unaudited)

(in thousands of Canadian dollars)

	Note	Six months ended	
		June 30 2013 \$	June 30 2012 \$
<b>Cash flow provided by (used in)</b>			
<b>Operating activities</b>			
Loss and comprehensive loss for the period		(5,117)	(4,399)
Adjustments for:			
Depreciation on property, plant, and equipment		102	94
Amortization of intangible assets		12	12
Share-based compensation	8, 10	106	123
Changes in items of working capital :			
Trade and other receivables		27	(125)
Inventories		(141)	50
Prepayments		(85)	133
Trade and other payables		12	35
Deferred revenue		(49)	(11)
<b>Net cash used in operating activities</b>		<b>(5,133)</b>	<b>(4,088)</b>
<b>Investing activities</b>			
Property, plant and equipment expenditures		(236)	(140)
Redemption of short-term investment		5,137	5,086
Purchase of short-term investment		(5,189)	(5,102)
<b>Net cash used in investing activities</b>		<b>(288)</b>	<b>(156)</b>
<b>Financing activities</b>			
Private placement	12	5,455	-
<b>Net cash provided by financing activities</b>		<b>5,455</b>	<b>-</b>
Increase(decrease) in cash and cash equivalents		34	(4,244)
		5,425	13,470
<b>Cash and cash equivalents, end of period</b>		<b>5,459</b>	<b>9,226</b>

The accompanying notes are an integral part of these unaudited condensed interim financial statements.

# Spectral Diagnostics Inc.

Notes to the Condensed Interim Financial Statements  
For the six months ended June 30, 2013 and 2012  
(Unaudited)

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(in thousands of Canadian dollars, except for share and per share data)

## 1. Nature of operations

Spectral Diagnostics Inc. (Spectral or the Company) was incorporated on July 29, 1991 in Ontario, Canada. The address of the registered office is 135-2 The West Mall, Toronto, Ontario. The Company is strategically focused on the development and commercialization of a treatment for severe sepsis and septic shock utilizing its Endotoxin Activity Assay (EAA™) diagnostic and the Toraymyxin therapeutic.

These condensed interim financial statements were approved for issue by the Board of Directors on August 12, 2013. These condensed interim financial statements have not been audited.

## 2. Basis of preparation

These condensed interim financial statements for the six months ended June 30, 2013 and 2012 have been prepared in accordance with Canadian generally accepted accounting principles ("Canadian GAAP"), defined as International Financial Reporting standards ("IFRS") as set out in the Handbook of the Canadian Institute of Chartered Accountants applicable to the preparation of interim financial statements, including IAS 34, "Interim Financial Reporting". The condensed interim financial statements should be read in conjunction with the annual financial statements for the year ended December 31, 2012, which have been prepared in accordance with Canadian GAAP.

## 3. Significant accounting policies

The accounting policies adopted are consistent with those of the previous financial year.

## 4. Estimates

The preparation of interim financial statements requires management to make judgments, estimates and assumptions that affect the application of accounting policies and the reported amounts of assets and liabilities, income and expense. Actual results could differ from those estimates.

In preparing these condensed interim financial statements, the significant judgments made by management in applying the accounting policies and the key sources of estimation and uncertainty were the same as those that applied to the financial statements for the year ended December 31, 2012.



# Spectral Diagnostics Inc.

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## 5. Accounting standards issued but not yet applied

There are no new IFRSs or IFRICs that are effective for the first time for this interim period that would be expected to have a material impact on the Company.

## 6. Financial risk management

### a. Financial risk

In the normal course of business, the Company is exposed to a number of financial risks that can affect its operating performance. These risks are: market risk (including currency risk, fair value interest rate risk, cash flow interest rate risk and price risk), credit risk and liquidity risk.

The condensed interim financial statements do not include all financial risk management information and disclosures required in the annual financial statements. They should be read in conjunction with the annual financial statements as at December 31, 2012. There have been no changes in the risk management since year end or in any risk management policies.

The Company's management continues to use prudent business practices to minimize any potential adverse effects on the Company's financial performance.

### b. Liquidity risk

There has been no material change since the Company's year end.

## 7. Commitments

The Company has committed to expenditures of approximately \$4,900 in the next twelve months and another \$3,300 in the two years thereafter for its U.S. pivotal trial. These expenditures represent estimated costs to the end of the trial, as it is currently configured.

## 8. Share-based compensation

The Company granted the following share options to directors, officers, employees and others at the discretion of the Board of Directors.

June 30 2013			June 30 2012		
Date	Number of share options	Exercise price	Date	Number of share options	Exercise price
February 7, 2013	950,000	\$0.210	January 17, 2012	860,000	\$0.285
May 1, 2013	100,000	\$0.200	May 18, 2012	95,000	\$0.200

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The exercise prices of the share options are equal to the closing market price of the Company's shares on the Toronto Stock Exchange on the immediately preceding day of the grant of the option. Share options issued to the Company's directors were vested at the time of the grant. Share options issued to the Company's officers in 2013 vested at 25% of the grant amount at the time of the grant. The balance of the officers' share options vest equally in each successive quarter and will be fully vested by February 7, 2016. Share options issued to the Company's officers and employees in 2012 vested at 25% of the grant amount at the time of the grant. The balance of these share options vest equally in each successive quarter and will be fully vested by January 17, 2015 and May 18, 2015 respectively. The contractual life of each share option is five years. There is no cash settlement of the share options.

The volatility measured at the standard deviation of continuously compounded share returns is based on statistical analysis of weekly share prices over the last five years.

Share options granted were valued using the Black-Scholes option pricing model, with the following assumptions:

	June 30, 2013		June 30, 2012	
	May 1 2013	February 7 2013	May 18 2012	January 17 2012
Risk-free interest rate	1.15%	1.48%	1.42%	1.26%
Expected life	5 years	5 years	5 years	5 years
Annualized volatility	84.88%	85.99%	88.92%	89.74%
Dividend rate	0%	0%	0%	0%
Grant date fair value	\$0.200	\$0.210	\$0.200	\$0.275

## 9. The EUPHRATES trial

The EUPHRATES (Evaluating the Use of Polymyxin B Hemoperfusion in a Randomized controlled trial of Adults Treated for Endotoxemia and Septic shock) trial is a randomized, double-blind control trial of standard of care versus standard of care and Toraymyxin, directed by Spectral's EAA™, an FDA cleared assay for use in sepsis.

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The Company has incurred the following costs associated with this clinical trial:

	Three months ended		Six months ended	
	2013	June 30 2012	2013	June 30 2012
	\$	\$	\$	\$
Program management	1,152	816	1,848	1,598
Program oversight	38	77	119	192
Clinical site costs	854	231	1,260	467
Diagnostic supply and training	137	63	257	129
Employee benefits	125	89	218	183
Consultants	36	-	128	-
<b>Total EUPHRATES</b>	<b>2,342</b>	<b>1,276</b>	<b>3,830</b>	<b>2,569</b>

The trial costs have been included in the statement of loss and comprehensive loss where applicable.

A program management fee deposit of US\$215 was made to the clinical research organization (CRO) responsible for the overall management of the EUPHRATES trial. As at June 30, 2013 US\$108 has been credited against services rendered during the period. The remaining US\$107 will be credited back to the Company when 75% of the total contracted services (US\$3,114) have been rendered. In the event the contract should be terminated prematurely, and a termination fee is determined to be payable to the CRO, the remaining deposit, if any, will be surrendered to the CRO.

## 10. Employee benefits

Key management includes the Company's directors and officers. Compensation awarded to key management included:

	Three months ended		Six months ended	
	June 30, 2013		June 30, 2013	
	\$		\$	
	All employees	Key management	All employees	Key management
Salaries	537	260	1,027	527
Short term employee benefits	70	19	141	48
Directors fees	62	62	122	122
Post-employment benefits	-	-	42	42
Share-based compensation	29	28	106	101
Other	16	12	16	12
	<b>714</b>	<b>381</b>	<b>1,454</b>	<b>852</b>

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	Three months ended June 30 2012		Six months ended June 30 2012	
	\$		\$	
	All employees	Key management	All employees	Key management
Salaries	498	275	1,010	564
Short term employee benefits	66	16	128	45
Directors fees	42	42	97	97
Post-employment benefits	-	-	42	42
Share- based compensation	31	24	123	104
Other	4	3	6	3
	<b>641</b>	<b>360</b>	<b>1,406</b>	<b>855</b>

## 11. Related party transactions

- i. The Company entered into a consulting services agreement with Medwell Capital Corp. ("Medwell"), effective January 1, 2010, and later amended on January 1, 2011. Under the terms of the agreement, Medwell was paid \$1,500 per annum plus applicable expenses from January 1, 2011 through July 31, 2012. Effective August 1, 2012, pursuant to a restructuring of the services agreement, Medwell was being paid \$400 per annum plus up to \$50 of applicable expenses to December 31, 2013. The Company provided notice of termination of the agreement, effective May 14, 2013. A termination fee of \$125 was paid on that date, representing 50% of remaining amounts due under the contract to December 31, 2013.

As at June 30, 2013, the amount owing to Medwell was \$nil (2012: \$299).

- ii. Compensation of key management is disclosed in Note 10.
- iii. As of June 30, 2013, Birch Hill Equity Partners Management Inc. ("Birch Hill") owns directly 11,252,053 common shares which represents 8.49% of the outstanding common shares of Spectral (calculated on a non-diluted basis). In addition, Birch Hill owns approximately 45% of the issued and outstanding common shares of Medwell, which entity owns approximately 11.5% of Spectral common shares outstanding. There are no related party transactions with Birch Hill.
- iv. Immediately after the closing of the Private placement, as described in Note 12, Toray Industries, Inc. owns 16,666,667 Common Shares, representing approximately 12.6% of the issued and outstanding common shares of the Company, calculated on a non-diluted basis.

The following table provides the total amount of transactions that have been entered into with Toray Industries, Inc. and its subsidiaries during the period from April 2, 2013 to June 30, 2013 as well as any amounts owed as at June 30, 2013.

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	Revenue \$	Amounts owed by \$
Toray Medical Co., Ltd.	42	-
Toray International Italy S.r.l.	51	-

There are no other related party transactions.

## 12. Private placement

On April 2, 2013, the Company completed a private placement financing, whereby the Company issued 18,666,667 common shares in the capital of the Company ("Common Shares"), at a price of \$0.30 per Common Share, to three investors for aggregate gross proceeds of \$5,600 ("the Private Placement"). The Company received net proceeds of \$5,455 which will be used to continue to support the Company's EUPHRATES clinical trial and for general corporate purposes.

As part of the Private Placement, Toray Industries, Inc. ("Toray") acquired 16,666,667 Common Shares at a price of \$0.30 per Common Share, for \$5,000.



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