

## **SPECTRAL ANNOUNCES FIRST QUARTER 2013 RESULTS**

**TORONTO, Canada – May 15, 2013 – Spectral Diagnostics Inc., (TSX:SDI / OTCQX: DIAGF)**, a Phase III company developing the first theranostic treatment for patients with septic shock, today announced its unaudited financial results for the first quarter ended March 31, 2013.

### **First Quarter Highlights:**

- Continued enrolling patients into the Company's Phase III EUPHRATES trial at a per site rate that is higher than previous sepsis trials. 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 currently targeted to enroll 306 evaluable patients at up to 60 sites in North America. Contingent on maintaining current enrolment rates and timely site start ups, the trial should be fully enrolled by the end of 2014. As of May 14, 2013, 116 patients have been randomized into Spectral's EUPHRATES trial.
- Announced that the first interim analysis has been conducted on the initial 76 randomized patients in its EUPHRATES trial. The Data and Safety 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 state 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 state that the EUPHRATES clinical protocol appears to be defining the correct target patient population for this study.
- Concluded the reporting period with approximately \$7,576,000 in cash, cash equivalents and short-term investments. Subsequent to quarter end, the Company announced it closed a private placement for gross proceeds of \$5.6 million. Under the terms of the private placement, Spectral issued 16,666,667 common shares in the capital of the Company to Toray Industries Inc. at a price of \$0.30 per common share, for gross proceeds of \$5,000,000. Other investors subscribed for an additional \$600,000 under the same terms, bringing the total private placement gross proceeds to \$5,600,000. The net proceeds of the private placement will be used to continue to support the Company's EUPHRATES clinical trial and for general operating purposes. Toray's investment represents approximately 12.8% of the issued and outstanding common shares of Spectral, calculated on a non-diluted basis.
- Subsequent to quarter end, 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 and expansion of commercial opportunities for Toraymyxin and Spectral's Endotoxin Activity Assay (EAA™) in Canada, the United States and Europe.

"During the past few months, we solidified our cash position and strengthened our existing collaborative relationship with Toray Industries," said Dr. Paul Walker, President and CEO of Spectral Diagnostics. "On the clinical front, we continued to steadily enroll patients into our pivotal Phase III trial and are now less than a year away from our second planned interim analysis of the trial data."

The second interim analysis will occur after 184 randomized patients have been followed for 28 days. At the second analysis, the trial's DSMB 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 remains on track to disclose information from the second interim analysis in the first half of 2014.

## Financial Review

Revenue for the three months ended March 31, 2013 was \$708,000 compared to \$676,000 for the same period in the preceding year, representing an increase of 4.7%.

Revenue was positively impacted by the revised terms of certain EAA™ distribution agreements that took effect during 2012. It is anticipated that revenue in 2013 will be consistent with levels achieved in 2012.

Operating costs for the three months ended March 31, 2013 were \$2,807,000 compared to \$2,976,000 in the first quarter of 2012. This represents a decrease of \$169,000. The Company continues to maintain a low-cost operating structure and expects no material increase in non-clinical operating costs in 2013.

The Company concluded the first quarter of 2013 with cash, cash equivalents and short-term investment of \$7,576,000 compared to \$10,562,000 as at December 31, 2012. On April 2, 2013, the Company closed a private placement for gross proceeds of \$5.6 million. The cash balance immediately following the private placement was \$12,955,000.

## About Spectral Diagnostics

Spectral is a Phase III company seeking U.S. FDA approval for its lead theranostics product for the treatment of severe sepsis with septic shock. Toraymyxin is a therapeutic hemoperfusion device that removes endotoxin, which can cause sepsis, from the bloodstream. Directed by the Company's Endotoxin Activity Assay (EAA™), the only FDA cleared diagnostic for the risk of developing sepsis. Spectral's EUPHRATES trial is the world's first theranostics trial in the area of sepsis.

Toraymyxin has been approved for therapeutic use in Japan and Europe, and has been used safely and effectively on more than 100,000 patients to date. In March 2009, Spectral obtained the exclusive development and commercial rights in the U.S. for Toraymyxin, and in November 2010, signed an exclusive distribution agreement for this product in Canada. More than 250,000 patients are diagnosed with severe sepsis and septic shock in North America each year, representing a greater than \$1 billion market opportunity for Spectral. Spectral is listed on the Toronto Stock Exchange under the symbol SDI, and on the OTCQX under the symbol DIAGF. For more information please visit [www.spectraldx.com](http://www.spectraldx.com)

## Forward-looking statement

*Information in this news release that is not current or historical factual information may constitute forward-looking information within the meaning of securities laws. Implicit in this information, particularly in respect of the future outlook of Spectral and anticipated events or results, are assumptions based on beliefs of Spectral's senior management as well as information currently available to it. While these assumptions were considered reasonable by Spectral at the time of preparation, they may prove to be incorrect. Readers are cautioned that actual results are subject to a number of risks and uncertainties, including the availability of funds and resources to pursue R&D projects, the successful and timely completion of clinical studies, the ability of Spectral to take advantage of business opportunities in the biomedical industry, the granting of necessary approvals by regulatory authorities as well as general economic, market and business conditions, and could differ materially from what is currently expected.*

*The TSX has not reviewed and does not accept responsibility for the adequacy or accuracy of this statement.*

For further information please contact:

Anthony Businkas  
Executive Vice President and CFO  
416-626-3233 ext. 2200

Adam Peeler  
Investor Relations  
TMX Equicom  
416-815-0700 ext. 225

## Spectral Diagnostics Inc.

### Condensed Interim Statement of Financial Position

---

(in thousands of Canadian dollars)

	March 31 2013 \$	December 31 2012 \$
	Unaudited	Audited
<b>Assets</b>		
<b>Current assets</b>		
Cash and cash equivalents	2,403	5,425
Short-term investment	5,173	5,137
Trade and other receivables	673	590
Inventories	418	277
Prepayments	647	226
	9,314	11,655
<b>Non-current assets</b>		
<b>Property, plant and equipment</b>	578	497
Intangible assets	428	434
	1,006	931
<b>Total assets</b>	10,320	12,586
<b>Liabilities</b>		
<b>Current liabilities</b>		
Trade and other payables	1,672	1,913
<b>Deferred revenue</b>	74	99
<b>Total liabilities</b>	1,746	2,012
<b>Equity</b>		
Share capital	27,101	27,101
<b>Contributed surplus</b>	3,864	3,864
<b>Other equity reserves</b>	8,337	8,260
Deficit	(30,728)	(28,651)
<b>Total equity</b>	8,574	10,574
<b>Total liabilities and equity</b>	10,320	12,586

## Spectral Diagnostics Inc.

Condensed Interim Statement of Loss and Comprehensive Loss  
For the three months ended March 31, 2013 and 2012  
(Unaudited)

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

	2013 \$	2012 \$
<b>Revenue</b>	708	676
<b>Other income</b>	5	36
<b>Expenses</b>		
Changes in inventories of finished goods and work- in- process	83	99
Raw materials and consumables used	111	99
Employee benefits	740	765
Consulting and professional fees	1,304	1,190
Management services	100	375
Regulatory and investor relations	48	123
Travel and entertainment	219	146
Depreciation and amortization	55	51
Foreign exchange loss	9	11
Other expenses	138	117
	2,807	2,976
<b>Operating loss</b>	(2,094)	(2,264)
Finance income	17	16
<b>Loss and comprehensive loss for the period</b>	(2,077)	(2,248)
<b>Basic and diluted loss per common share</b>	(0.02)	(0.02)
<b>Weighted average number of common shares outstanding</b>	113,883,394	113,883,394



# Spectral Diagnostics Inc.

Condensed Interim Statement of Changes in Equity  
(Unaudited)

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

	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	-	-	-	-	-	(2,248)	(2,248)
Share-based compensation	-	-	-	92	-	-	92
<b>Balance, March 31, 2012</b>	113,883,394	27,101	3,864	3,031	5,143	(22,356)	16,783
<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	-	-	-	-	-	(2,077)	(2,077)
Share-based compensation	-	-	-	77	-	-	77
<b>Balance, March 31, 2013</b>	113,883,394	27,101	3,864	3,194	5,143	(30,728)	8,574

# Spectral Diagnostics Inc.

Condensed Interim Statement of Cash Flows

For the three months ended March 31, 2013 and 2012

(Unaudited)

(in thousands of Canadian dollars)

	2013 \$	2012 \$
<b>Cash flow provided by (used in)</b>		
<b>Operating activities</b>		
Loss and comprehensive loss for the period	(2,077)	(2,248)
Adjustments for:		
Depreciation on property, plant, and equipment	48	45
Amortization of intangible assets	6	6
Share-based compensation	77	92
Changes in items of working capital :		
Trade and other receivables	(83)	(266)
Inventories	(141)	36
Prepayments	(421)	(161)
Trade and other payables	(241)	17
Deferred revenue	(25)	(26)
<b>Net cash used in operating activities</b>	<b>(2,857)</b>	<b>(2,505)</b>
<b>Investing activities</b>		
Property, plant and equipment expenditures	(129)	(72)
Redemption of short-term investment	5,137	5,086
Purchase of short-term investment	(5,173)	(5,102)
<b>Net cash used in investing activities</b>	<b>(165)</b>	<b>(88)</b>
<b>Decrease in cash and cash equivalents</b>	<b>(3,022)</b>	<b>(2,593)</b>
<b>Cash and cash equivalents, beginning of period</b>	<b>5,425</b>	<b>13,470</b>
<b>Cash and cash equivalents, end of period</b>	<b>2,403</b>	<b>10,877</b>