



## SPECTRAL ANNOUNCES THIRD QUARTER 2013 RESULTS

**TORONTO, Canada – November 13, 2013 – Spectral Diagnostics Inc., (TSX:SDI) (OTCQX: DIAGF),** a Phase III company developing the first theranostic treatment for patients with severe sepsis and septic shock, today announced its unaudited financial results for the third quarter ended September 30, 2013.

### Third Quarter Highlights:

- Continued to enroll patients into the Company's Phase III EUPHRATES trial at an accelerated rate. 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, as currently configured, is targeted to enroll 306 evaluable patients in North America. At current enrollment rates, these patients would be enrolled by the end of the second quarter of 2014.
- Announced that the 184 patients required for the trial's planned, second interim analysis have been randomized. The 184 patients have now been followed for 28 days and all data is in the process of being gathered and analyzed. The Data and Safety Monitoring Board (DSMB) will review the data and the overall progress of the trial and advise Spectral on the trial's safety, futility and efficacy, with stopping rules in place for efficacy.
- Disclosed that the composite 28-day mortality rate of 33 percent for randomized patients in the trial continues to suggest that the trial is enrolling patients who are at greatest risk for a poor medical outcome and, therefore, would most likely benefit from the Company's theranostic treatment.
- As of November 12, 2013, 206 patients had been randomized into Spectral's EUPHRATES trial.

"We continued to enroll patients at an accelerated rate during the quarter," stated Dr. Paul Walker, President and CEO of Spectral. "We are very excited about learning the upcoming results of our data-rich, planned second interim analysis because we believe they should support the successful completion of the trial."

Spectral remains on track to disclose information from the second interim analysis in early 2014.

The second interim analysis will include, if needed, a sample size recalculation which will be based on the observed clinical trial data so far and will set a sample size that is required to attain a statistically and clinically significant difference in the mortality between the treated and placebo groups. This sample size recalculation, if needed, will also determine the expected timing for trial completion.

### Financial Review

Revenue for the three months ended September 30, 2013 was \$679,000, compared to \$667,000 for the same period in the preceding year. For the nine months ended September 30, 2013 revenue was \$1,959,000 compared to \$1,942,000 for the same period in 2012.

Total expenses for the three months ended September 30, 2013 were \$3,217,000 compared to \$2,787,000 in the third quarter of 2012. For the nine months ended September 30, 2013 total expenses were \$9,666,000 compared to \$8,561,000 for the same prior-year period. This increase of \$1,105,000 for the nine months ended September 30, 2013 is directly attributable to the higher EUPHRATES trial costs of \$1,845,000 mitigated by a \$648,000 decrease in management services fees and other operating costs.

The Company continues to maintain a low-cost operating structure and expects no material increase in non clinical operating costs for the remainder of 2013.

For the quarter ended September 30, 2013, the Company reported a loss of \$2,517,000 compared to a loss of \$2,077,000 for the corresponding period in 2012. For the nine months ended September 30, 2013, Spectral reported a loss of \$7,634,000 compared to \$6,476,000 for the same period in 2012. The Company's loss was greater for the three and nine months of 2013 primarily due to higher costs for its EUPHRATES trial.

Spectral concluded the third quarter of 2013 with cash, cash equivalents and short-term investment of \$9,044,000 compared to \$10,562,000 as at December 31, 2012. Subsequent to the quarter end, the Company received \$585,000 cash on the exercise of 1,462,500 share purchase warrants at an exercise price of \$0.40 per common share.

The total number of shares outstanding for the Company was 133,000,061 as at September 30, 2013.

### **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 only active and most innovative Phase III study in the area of septic shock.

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. Approximately 350,000 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  
Spectral Diagnostics Inc.  
416-626-3233 ext. 2200  
[tbusinkas@spectraldx.com](mailto:tbusinkas@spectraldx.com)

Adam Peeler  
Investor Relations  
TMX Equicom  
416-815-0700 ext. 225  
[apeeler@tmxequicom.com](mailto:apeeler@tmxequicom.com)

# Spectral Diagnostics Inc.

## Condensed Interim Statement of Financial Position

(in thousands of Canadian dollars)

	September 30 2013 \$ Unaudited	December 31 2012 \$ Audited
<b>Assets</b>		
<b>Current assets</b>		
Cash and cash equivalents	3,855	5,425
Short-term investment	5,189	5,137
Trade and other receivables	510	590
Inventories	357	277
Prepayments	305	226
	10,216	11,655
<b>Non-current assets</b>		
<b>Property, plant and equipment</b>	620	497
Intangible assets	416	434
	1,036	931
<b>Total assets</b>	11,252	12,586
<b>Liabilities</b>		
<b>Current liabilities</b>		
Trade and other payables	2,527	1,913
Deferred revenue	25	99
<b>Total liabilities</b>	2,552	2,012
<b>Equity</b>		
Share capital	32,692	27,101
Contributed surplus	3,864	3,864
Other equity reserves	8,429	8,260
Deficit	(36,285)	(28,651)
<b>Total equity</b>	8,700	10,574
<b>Total liabilities and equity</b>	11,252	12,586

# Spectral Diagnostics Inc.

Condensed Interim Statement of Loss and Comprehensive Loss  
For the nine months ended September, 2013 and 2012  
(Unaudited)

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

	Three months ended September 30		Nine months ended September 30	
	2013	2012	2013	2012
	\$	\$	\$	\$
<b>Revenue</b>	679	667	1,959	1,942
<b>Other income</b>	5	25	24	91
<b>Expenses</b>				
Changes in inventories of finished goods and work- in-process	114	64	235	208
Raw materials and consumables used	133	135	414	344
Employee benefits	719	598	2,173	2,004
Consulting and professional fees	1,793	1,352	4,971	3,598
Management services	-	173	275	923
Regulatory and investor relations	48	112	154	334
Travel and entertainment	228	153	898	612
Depreciation and amortization	62	57	176	163
Foreign exchange (gain)loss	4	16	4	20
Other expenses	116	127	366	355
	3,217	2,787	9,666	8,561
<b>Operating loss</b>	(2,533)	(2,095)	(7,683)	(6,528)
Finance income	16	18	49	52
<b>Loss and comprehensive loss for the period</b>	(2,517)	(2,077)	(7,634)	(6,476)
<b>Basic and diluted loss per common share</b>	(0.02)	(0.02)	(0.06)	(0.06)
<b>Weighted average number of common shares outstanding</b>	132,669,898	113,883,394	126,299,847	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	-	-	-	-	-	(6,476)	(6,476)
Share-based compensation	-	-	-	150	-	-	150
<b>Balance, September 30, 2012</b>	113,883,394	27,101	3,864	3,089	5,143	(26,584)	12,613
<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	-	-	-	-	-	(7,634)	(7,634)
Private placement	18,666,667	5,455	-	-	-	-	5,455
Share options exercised	450,000	136	-	-	-	-	136
Share-based compensation	-	-	-	169	-	-	169
<b>Balance, September 30, 2013</b>	133,000,061	32,692	3,864	3,286	5,143	(36,285)	8,700

# Spectral Diagnostics Inc.

Condensed Interim Statement of Cash Flows

For the nine months ended September 30, 2013 and 2012

(Unaudited)

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

	Nine months ended	
	September 30	September 30
	2013	2012
	\$	\$
<b>Cash flow provided by (used in)</b>		
<b>Operating activities</b>		
Loss and comprehensive loss for the period	(7,634)	(6,476)
Adjustments for:		
Depreciation on property, plant, and equipment	158	145
Amortization of intangible assets	18	18
Share-based compensation	169	150
Changes in items of working capital :		
Trade and other receivables	80	(96)
Inventories	(80)	82
Prepayments	(79)	245
Trade and other payables	614	(103)
Deferred revenue	(74)	(76)
<b>Net cash used in operating activities</b>	<b>(6,828)</b>	<b>(6,111)</b>
<b>Investing activities</b>		
Property, plant and equipment expenditures	(281)	(214)
Redemption of short-term investment	5,137	5,086
Purchase of short-term investment	(5,189)	(5,137)
<b>Net cash used in investing activities</b>	<b>(333)</b>	<b>(265)</b>
<b>Financing activities</b>		
Private placement	5,455	-
Share options exercised	136	-
<b>Net cash provided by financing activities</b>	<b>5,591</b>	<b>-</b>
<b>Increase(decrease) in cash and cash equivalents</b>	<b>(1,570)</b>	<b>(6,376)</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>3,855</b>	<b>7,094</b>