



May 16, 2016

## **Sophiris Bio Reports First Quarter 2016 Financial Results and Key Business Highlights**

SAN DIEGO and VANCOUVER, British Columbia, May 16, 2016 /PRNewswire/ -- Sophiris Bio Inc. (NASDAQ: SPHS) (the "Company" or "Sophiris"), a biopharmaceutical company developing topsalysin (PRX302) for the treatment of urological diseases, today announced financial results for the three months ended March 31, 2016.

### **Business Highlights:**

- 1 On May 12, 2016, the Company announced the engagement Oppenheimer & Co. Inc. as its financial advisor to assist with the evaluation of various strategic alternatives.
- 1 On May 11, 2016, the Company announced the closing of a public offering of common shares and warrants in which the Company raised net proceeds of \$4.6 million.
- 1 On May 7, 2016, the Company presented positive data from its Phase 3 clinical trial of topsalysin as a treatment for the symptoms of benign prostatic hyperplasia ("BPH") as a late breaking poster at the 111<sup>th</sup> American Urological Association Annual Meeting. A copy of the poster is available on the Company's website at [www.sophirisbio.com](http://www.sophirisbio.com).
- 1 On January 28, 2016, the Company announced that a review of the 6-month biopsy data from the first seven patients in the localized prostate cancer trial was completed.

"We are encouraged by the interim data from our Phase 2a topsalysin proof of concept trial for the treatment of localized prostate cancer announced earlier this year, and remain on track to complete this clinical trial by the end of this quarter," stated Randall Woods, president and CEO of Sophiris Bio. "We believe that the positive data from our Phase 3 BPH clinical trial and the encouraging initial data from our localized prostate cancer clinical trial further de-risk the development programs."

Mr. Woods added: "The funds raised in the financing strengthen our balance sheet as we review various strategic alternatives to advance the clinical development of topsalysin and create value for shareholders."

### **Phase 2a Proof of Concept Clinical Trial for Localized Prostate Cancer:**

In May 2015 we initiated a single-center, open-label Phase 2a proof of concept clinical trial ("POC trial") of topsalysin for the treatment of localized low to intermediate risk prostate cancer. We believe that the highly targeted mechanism by which topsalysin selectively destroys prostate tissue in BPH makes topsalysin a potential targeted focal treatment for localized prostate cancer. A total of 18 patients with clinically significant, localized low to intermediate risk prostate cancer have been enrolled in this ongoing POC trial.

On January 28, 2016 we announced the biopsy data at six months on the first seven patients to complete the POC trial. A review of the biopsy data from the first seven patients showed that four patients experienced a response to treatment, including: one patient who experienced complete ablation of the tumor where there was no evidence of the treated tumor on a targeted biopsy at six months following treatment; and three patients who experienced either a reduction in the maximum cancer core length or a reduction in the Gleason pattern. Three patients had no response to treatment. No serious adverse events have been observed to date in this clinical trial and no new safety signals have been reported. We expect to have final data on all 18 patients by the end of the second quarter of 2016.

### **Financial Results:**

At March 31, 2016, we had cash, cash equivalents and securities available-for-sale of \$5.4 million and net working capital of \$3.0 million. Taking into consideration the net proceeds of \$4.6 million from our financing completed on May 11, 2016, we now expect that our cash, cash equivalents and securities available-for-sale will be sufficient to fund our operations for at least the next twelve months assuming that we do not initiate any additional clinical development of topsalysin beyond our on-going Phase 2a POC trial. We will need to obtain additional capital to fund a second Phase 3 clinical trial of topsalysin for the treatment of the symptoms of BPH and for any future clinical development of topsalysin for the treatment of localized prostate cancer and to fund our ongoing operations. We are actively evaluating strategic alternatives, including potential partnering arrangements, financings or a strategic transaction. We expect our research and development expense and

general and administrative expenses to decrease as a result of the completion of our Phase 2a POC trial at the end of the second quarter of 2016 and as a result of the layoff of five of our ten employees during May 2016, resulting in an annualized reduction in compensation and benefit expenses of \$0.9 million, net of severance. As of March 31, 2016, the outstanding principal balance of our term loan was \$4.8 million on which we make principal and interest payments monthly.

The Company reported a net loss of \$2.2 million (\$0.13 per share) for the three months ended March 31, 2016 compared to a net loss of \$4.3 million (\$0.26 per share) for the three months ended March 31, 2015.

#### *Research and development expenses*

Research and development expenses were \$0.9 million for the three months ended March 31, 2016 compared to \$3.1 million for the three months ended March 31, 2015. The decrease in research and development costs is attributable to decreases in the costs associated with the Company's completed Phase 3 PLUS-1 clinical trial of topsalysin, costs associated with the manufacturing activities for topsalysin and personnel related costs. These decreases are partially offset by an increase in costs associated with the Phase 2a POC trial for localized low to intermediate risk prostate cancer which enrolled its first patient in the second quarter of 2015.

#### *General and administrative expenses*

General and administrative expenses were \$1.2 million for the three months ended March 31, 2016 compared to \$1.0 million for the three months ended March 31, 2015. The increase is primarily due to increases in legal, accounting and professional services costs.

### **About Sophiris**

Sophiris Bio Inc. is a biopharmaceutical company developing topsalysin, a clinical-stage, targeted therapy for the treatment of urological diseases. Topsalysin is in Phase 3 clinical development for the treatment of the symptoms of benign prostatic hyperplasia (BPH) and is designed to be as efficacious as pharmaceuticals, less invasive than the surgical interventions, and without the sexual side effects seen with existing treatments. Topsalysin is also currently in a Phase 2a POC trial for the treatment of localized low to intermediate risk prostate cancer. For more information, please visit [www.sophiris.com](http://www.sophiris.com).

*Certain statements included in this press release may be considered forward-looking, including the quote of Sophiris' President and CEO and any expectations relating to the review of strategic alternatives, the potential completion of a transaction or the results of the Phase 2a POC trial for the treatment of localized low to intermediate risk prostate cancer and expectations about efficacy of PRX302, the timing of receipt of data from the proof of concept trial or Sophiris' capital requirements and ability to raise capital or enter into a development agreement and continue to operate as a going concern. Such statements involve known and unknown risks, uncertainties and other factors that may cause actual results, performance or achievements to be materially different from those implied by such statements, and therefore these statements should not be read as guarantees of future performance or results. Some of the risks and uncertainties that could cause actual results, performance or achievements to differ include without limitation, risks associated with various strategic alternatives, including risks relating to raising capital and risks finding a development or strategic partner and negotiating a development or other strategic agreement, and other risks and uncertainties identified by Sophiris in its public securities filings with the SEC. All forward-looking statements are based on Sophiris' current beliefs as well as assumptions made by and information currently available to Sophiris and relate to, among other things, anticipated financial performance, business prospects, strategies, regulatory developments, clinical trial results, market acceptance, ability to raise capital and future commitments. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this press release. Due to risks and uncertainties, including the risks and uncertainties identified by Sophiris in its public securities filings; actual events may differ materially from current expectations. Sophiris disclaims any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.*

**Sophiris Bio Inc.**  
**Condensed Consolidated Balance Sheets**  
(In thousands, except share amounts)  
(Unaudited)

	<u>March 31, 2016</u>	<u>December 31, 2015</u>
<b>Assets:</b>		
<b>Current assets:</b>		

Cash and cash equivalents	\$ 5,146	\$ 5,881
Securities available-for-sale	250	2,500
Other receivables	-	8
Prepaid expenses	430	467
<b>Total current assets</b>	<b>5,826</b>	<b>8,856</b>
Property and equipment, net	12	17
Other long-term assets	19	19
<b>Total assets</b>	<b>\$ 5,857</b>	<b>\$ 8,892</b>
<b>Liabilities and shareholders' (deficit) equity:</b>		
<b>Current liabilities:</b>		
Accounts payable	\$ 395	\$ 909
Accrued expenses	619	566
Current portion of promissory notes	1,824	1,771
<b>Total current liabilities</b>	<b>2,838</b>	<b>3,246</b>
Long-term promissory notes	3,096	3,572
Stock-based compensation liability	121	168
<b>Total liabilities</b>	<b>6,055</b>	<b>6,986</b>
<b>Shareholders' (deficit) equity:</b>		
Common shares, unlimited authorized shares, no par value; 17,244,736 shares issued and outstanding at March 31, 2016 and December 31, 2015	113,880	113,880
Contributed surplus	17,821	17,683
Accumulated other comprehensive gain	99	99
Accumulated deficit	(131,998)	(129,756)
<b>Total shareholders' (deficit) equity</b>	<b>(198)</b>	<b>1,906</b>
<b>Total liabilities and shareholders' (deficit) equity</b>	<b>\$ 5,857</b>	<b>\$ 8,892</b>

**Sophiris Bio Inc.**  
**Condensed Consolidated Statements of Operations and Comprehensive Loss**  
(In thousands, except per share amounts)  
(Unaudited)

	<b>Three Months Ended March 31,</b>	
	<b>2016</b>	<b>2015</b>
<b>Operating expenses:</b>		
Research and development	\$ 929	\$ 3,081
General and administrative	1,164	1,048
<b>Total operating expenses</b>	<b>2,093</b>	<b>4,129</b>
<b>Other income (expense):</b>		
Interest expense	(150)	(176)
Interest income	5	8
Other expense	(4)	(7)
<b>Total other expense</b>	<b>(149)</b>	<b>(175)</b>
<b>Net loss</b>	<b>\$ (2,242)</b>	<b>\$ (4,304)</b>

<b>Basic and diluted loss per share</b>	\$	<u>(0.13)</u>	\$	<u>(0.26)</u>
Weighted average number of outstanding shares - basic and diluted		<u>17,244</u>		<u>16,845</u>

To view the original version on PR Newswire, visit: <http://www.prnewswire.com/news-releases/sophiris-bio-reports-first-quarter-2016-financial-results-and-key-business-highlights-300269217.html>

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