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Sophiris Bio Reports First Quarter Financial Results and Key Corporate Highlights

SAN DIEGO and VANCOUVER, British Columbia, May 15, 2017 /PRNewswire/ -- Sophiris Bio Inc. (NASDAQ: SPHS) (the "Company" or "Sophiris"), a late stage clinical biopharmaceutical company developing topsalysin (PRX302) for the treatment of patients with urological diseases, today reported first quarter financial results and key corporate highlights.

Key Corporate Highlights:

- **Update on Phase 2b Localized Prostate Cancer Study**. In March 2017, the Company initiated its Phase 2b open-label localized prostate cancer study with investigational sites in both the UK and US. Five clinical trial sites have been initiated and additional sites are in the process of being initiated.

  The Company is currently awaiting final regulatory clearance for the diluent (the medium in which topsalysin is diluted prior to dosing), which is anticipated this month, at which point the investigational sites will begin dosing patients.

  The Company expects to receive the six-month biopsy data for all patients in the first quarter of 2018 assuming enrollment is completed as expected. The Company expects to have complete data on all patients who receive a second dose by the fourth quarter of 2018.

- **Presented Proof-of-Concept and Phase 2a Data at Global Urological Meetings.** The Company presented positive data from its Phase 2a clinical trial of topsalysin for the focal treatment of localized prostate cancer at the 112th American Urological Association Annual Meeting and at the 32nd European Association of Urology Congress. Copies of the posters are available on the Company's website at www.sophirisbio.com.

"We now have five clinical trial sites fully trained with additional sites coming onboard," said Randall E. Woods, president and CEO of Sophiris. "The regulatory approval of the diluent is the last remaining box to check in the administrative work that enables the dosing of patients which we anticipate being able to do in the very near future."

Financial Results:

At March 31, 2017, the Company had cash, cash equivalents and securities available-for-sale of $25.7 million and working capital of $25.6 million. The Company expects that its cash and cash equivalents will be sufficient to fund its operations through the end of 2018. The Company is currently not planning on pursuing a second Phase 3 trial in BPH, unless the Company can secure a development partner to fund a new clinical trial or the Company obtains other financing.

The Company reported a net loss of $2.6 million ($0.09 per share) for the three months ended March 31, 2017 compared to a net loss of $2.2 million ($0.13 per share) for the three months ended March 31, 2016.

Research and development expenses were $1.2 million for the three months ended March 31, 2017, compared to $0.9 million for the three months ended March 31, 2016. The increase in research and development expenses was primarily attributable to an increase in the costs associated with the Company's on-going Phase 2b clinical trial for the focal treatment of localized prostate cancer which was initiated in March 2017 and, to a lesser extent, an increase in costs associated with manufacturing activities for topsalysin. These increases were partially offset by a decrease in costs associated with our completed Phase 2a proof of concept clinical trial for low to intermediate risk prostate cancer.

General and administrative expenses were $1.4 million for the three months ended March 31, 2017 compared to $1.2 million for the three months ended March 31, 2016. The increase in general and administrative expenses was primarily due to an increase in non-cash stock-based compensation expense which was offset by a reduction in legal and professional services.

About Sophiris

Sophiris Bio Inc. is a late-stage clinical biopharmaceutical company developing topsalysin (PRX302) for the treatment of patients with urological diseases. Topsalysin is in Phase 2 clinical development for the focal treatment of localized prostate cancer as well as Phase 3 clinical development for the treatment of the lower urinary tract symptoms of benign prostatic hyperplasia (BPH). Topsalysin is a highly potent ablative agent that is selective and targeted in that it is only activated by enzymatically active PSA which is found in high concentrations in the transition zone of the prostate and in and around prostate tumor cells. More than 400 patients have received topsalysin, which continues to appear to be safe and well tolerated. For more information, please visit www.sophirisbio.com.

Certain statements included in this press release may be considered forward-looking, including the quote of Sophiris' President and CEO and expectations about further development of topsalysin (PRX302), including the timing of expected results, or Sophiris' liquidity or capital requirements. 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 clinical development, including the risk that the enrollment of the Phase 2b study will not be completed when expected and that results will not be available when expected and risks that the results of the Phase 2b study will not replicate the results of the completed Phase 2 study of topsalysin for the treatment of localized low to intermediate risk prostate cancer or the study endpoint[s] will not be achieved, 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.

Company Contact:
Peter Slover
Chief Financial Officer
(858) 777-1760

Corporate Communications Contact:
Jason Spark
Canale Communications
(619) 849-6005
jason@canalecomm.com

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

	March 31,	December 31,

	2017	2016
Assets:		
Current assets:		
Cash and cash equivalents	$ 8,894	$ 12,800
Securities available-for-sale	16,800	16,201
Other receivables	86	128
Prepaid expenses	959	846
Total current assets	26,739	29,975
Property and equipment, net	1	4
Other long-term assets	19	19
Total assets	$ 26,759	$ 29,998
Liabilities and shareholders' equity:		
Current liabilities:		
Accounts payable	$ 360	$ 459
Accrued expenses	765	1,762
Total current liabilities	1,125	2,221
Warrant liability	13,482	13,396
Stock-based compensation liability	23	57
Total liabilities	14,630	15,674
Shareholders' equity:		
Common shares, unlimited authorized shares, no par value; 30,111,153 and 30,107,644 shares issued and outstanding at March 31, 2017 and December 31, 2016, respectively	131,246	131,245
Contributed surplus	24,336	23,900
Accumulated other comprehensive gain	86	99
Accumulated deficit	(143,539)	(140,920)
Total shareholders' equity	12,129	14,324
Total liabilities and shareholders' equity	$ 26,759	$ 29,998

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

	Three Months Ended March 31,	
	2017	2016
Operating expenses:		
Research and development	$ 1,208	$ 929
General and administrative	1,369	1,164
Total operating expenses	2,577	2,093
Other income (expense):		
Interest expense	-	(150)
Interest income	51	5

Loss on revaluation of warrant liability	(86)	-
Other expense, net	(7)	(4)
Total other expense	(42)	(149)
Net loss	$ (2,619)	$ (2,242)
Basic and diluted loss per share	$ (0.09)	$ (0.13)
Weighted average number of outstanding shares - basic and diluted	30,111	17,244

To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/sophiris-bio-reports-first-quarter-financial-results-and-key-corporate-highlights-300457754.html

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