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Sophiris Bio Reports Second Quarter Financial Results and Key Corporate Highlights

SAN DIEGO and VANCOUVER, British Columbia, Aug. 10, 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 financial results for the three and six months ended June 30, 2017 and key corporate highlights.

Key Corporate Highlights:

- **Phase 2b Localized Prostate Cancer Study Underway**. On June 8, 2017, the Company announced that the first patient had been dosed in its Phase 2b study to evaluate the safety and tolerability of a single dose of topsalysin in focally treating men with clinically significant localized prostate cancer. Topsalysin (PRX302) is an innovative, first-in-class pore-forming protein engineered to be activated only in the presence of enzymatically-active PSA, which is only found within the prostate. This study is enrolling approximately 40 patients at clinical sites in the UK and US. The Company expects to receive the 24- week biopsy data for all patients from the first dose of topsalysin in the first quarter of 2018 assuming enrollment is completed as expected.

  The Phase 2b study includes an option to re-treat patients with a second dose of topsalysin, with a targeted biopsy to occur 24 weeks following the second dose. The Company expects to have complete data on all patients who receive a second dose by the fourth quarter of 2018 assuming enrollment is completed as expected.

- **Added to Russell Microcap Index®**. In June 2017, the Company was added to the Russell Microcap® Index. Russell indices are widely used by investment managers and institutional investors for index funds and as benchmarks for both passive and active investment strategies.
- **Filing of New Form S-3.** In anticipation of the expiration of the company's existing Form S-3 shelf registration statement filed in September 2014, Sophiris will file a new Form S-3 today with the Securities and Exchange Commission to register securities which could be issued in the future.

"Topsalysin is a highly potent ablative agent, which we administer by an ultrasound-guided injection directly into a tumor, previously confirmed by biopsy. We are using state of the art commercially available software in order to increase the precision by which the physician administers topsalysin into the pre-identified tumor," said Randall E. Woods, president and CEO of Sophiris. "We are working toward completion of enrollment, and we would like to thank the investigators, study coordinators and patients for their participation in this exciting study."

Financial Results:

At June 30, 2017, the Company had cash, cash equivalents and securities available-for-sale of $24.0 million and working capital of $23.4 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.

For the three months ended June 30, 2017

The Company reported net income of $0.6 million or $0.02 per share for the three months ended June 30, 2017 compared to a net loss of $4.1 million or ($0.21 per share) for the three months ended June 30, 2016. The net income for the three months ended June 30, 2017 was driven by a non-cash gain related to the revaluation of the Company's warrant liability. See an additional discussion below related to this item.

Research and development expenses

Research and development expenses were $1.4 million for the three months ended June 30, 2017, compared to $1.0 million for the three months ended June 30, 2016. The increase in research and development costs are primarily attributable to increases in the costs associated with the Company's Phase 2b clinical trial for the focal treatment of localized prostate cancer, costs associated with manufacturing activities for topsalysin and non-cash stock-based compensation expense. These increases are partially offset by decreases in costs associated with our completed Phase 2a proof of concept clinical trial for low to intermediate risk prostate cancer and personnel related costs.

General and administrative expenses

General and administrative expenses were $1.4 million for the three months ended June 30, 2017 and 2016. General and administrative expense included non-cash stock-based compensation expense of $0.3 million for the three months ended June 30, 2017 as compared to $0.1 million for the three months ended June 30, 2016. This increase was offset by decreases for personnel related costs.

Gain (loss) on revaluation of the warrant liability

Gain on revaluation of the warrant liability was $3.3 million for the three months ended June 30, 2017 compared to a loss of $1.6 million for the three months ended June 30, 2016. Because these warrants may require us to pay the warrant holder cash under certain provisions of the warrant, we account for these warrants as a liability and we are required to calculate the fair value of these warrants each reporting date. This non-cash gain is associated with a reduction in the fair value of the Company's warrant liability which is calculated using a Black-Scholes pricing model. Certain inputs utilized in the Company's Black-Scholes fair value calculation may fluctuate in future periods based upon factors which are outside of the Company's control. A significant change in one or more of these inputs used in the calculation of the fair value may cause a significant change to the fair value of the Company's warrant liability, which could also result in material non-cash gain or loss being reported in the Company's consolidated statement of operations and comprehensive loss.

For the six months ended June 30, 2017

The Company reported a net loss of $2.0 million or ($0.07 per share) for the six months ended June 30, 2017 compared to a net loss of $6.3 million or ($0.35 per share) for the six months ended June 30, 2016.

Research and development expenses

Research and development expenses were $2.6 million for the six months ended June 30, 2017 compared to $1.9 million for the six months ended June 30, 2016. The increase in research and development costs are primarily attributable to increases in the costs associated with the Company's Phase 2b for the focal treatment of localized prostate cancer, costs associated with the manufacturing activities for topsalysin and the non-cash stock-based compensation expense. These increases are partially offset by decreases in costs associated with our completed Phase 2a proof of concept clinical trial for low to intermediate risk prostate cancer and personnel related costs.

General and administrative expenses

General and administrative expenses were $2.7 million for the six months ended June 30, 2017 compared to $2.5 million for the six months ended June 30, 2016. The increase is primarily due to an increase in professional services and non-cash stock-based compensation expense. These increases are partially offset by the decreases in personnel related costs, legal and closing costs which were expensed as they were allocated to the warrants issued in our completed financing during the six months ended June 30, 2016.

Gain (loss) on revaluation of the warrant liability

Gain on revaluation of the warrant liability was $3.2 million for the six months ended June 30, 2017 as compared to a loss of $1.6 million for the six months ended June 30, 2016. This non-cash gain is associated with a reduction in the fair value of our warrant liability.

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, expectations about further development of topsalysin (PRX302), including the timing of expected results, statements about warrant liability and statements related to 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.

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

	June 30 2017	December 31, 2016
Assets:		
Current assets:		
Cash and cash equivalents	$ 6,824	$ 12,800
Securities available-for-sale	17,205	16,201
Other receivables	69	128
Prepaid expenses	948	846
Total current assets	25,046	29,975

Property and equipment, net	2	4
Other long-term assets	-	19
Total assets	$ 25,048	$ 29,998
Liabilities and shareholders' equity:		
Current liabilities:		
Accounts payable	$ 506	$ 459
Accrued expenses	1,154	1,762
Total current liabilities	1,660	2,221
Warrant liability	10,162	13,396
Stock-based compensation liability	-	57
Total liabilities	11,822	15,674
Shareholders' equity:		
Common shares, unlimited authorized shares, no par value; 30,111,153 and 30,107,644 shares issued and outstanding at June 30, 2017 and December 31, 2016, respectively	131,246	131,245
Contributed surplus	24,824	23,900
Accumulated other comprehensive gain	85	99
Accumulated deficit	(142,929)	(140,920)
Total shareholders' equity	13,226	14,324
Total liabilities and shareholders' equity	$ 25,048	$ 29,998

Sophiris Bio Inc.

Condensed Consolidated Statements of Operations and Comprehensive Income (Loss)

(In thousands, except per share amounts)

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	**2016**	**2017**	**2016**
Operating expenses:				
Research and development	$ 1,387	$ 978	$ 2,595	$ 1,907
General and administrative	1,367	1,357	2,736	2,521
Total operating expenses	2,754	2,335	5,331	4,428
Other income (expense):				
Interest expense	-	(137)	-	(287)
Interest income	53	3	103	7
Gain (Loss) on revaluation of warrant liability	3,320	(1,619)	3,234	(1,619)
Other expense, net	(9)	(3)	(16)	(7)
Total other income (expense)	3,364	(1,756)	3,321	(1,906)
Net income (loss)	$ 610	$ (4,091)	$ (2,010)	$ (6,334)
Basic income (loss) per share	$ 0.02	$ (0.21)	$ (0.07)	$ (0.35)
Diluted income (loss) per share	$ 0.02	$ (0.21)	$ (0.07)	$ (0.35)
Weighted average number of outstanding shares - basic	30,111	19,340	30,111	18,292
Weighted average number of outstanding shares -diluted	30,515	19,340	30,111	18,292

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