Sophiris Bio Reports Third Quarter 2019 Financial Results and Recent Corporate Highlights

November 7, 2019

SAN DIEGO and VANCOUVER, British Columbia, Nov. 07, 2019 (GLOBE NEWSWIRE) -- Sophiris Bio Inc. (NASDAQ: SPHS), a biopharmaceutical company studying topsalysin (PRX302), a first-in-class, pore-forming protein, in late-stage clinical trials for the treatment of patients with urological diseases, today reported financial results for the third quarter 2019 and provided an overview of recent corporate highlights.

"We took a significant step forward with the agreement of a Phase 3 trial design with the FDA for our localized prostate cancer program, a step that advances discussions around potential strategic agreements necessary to help fund the development of topsalysin," said Randall E. Woods, president and CEO of Sophiris. "The design agreed to with the FDA aligns with the design previously approved by the EMA which will allow us to complete a global Phase 3 program for the potential approval of topsalysin for treating patients with intermediate risk localized prostate cancer in both the US and Europe."

Recent Corporate Highlights:

- On August 30, 2019, the Company announced the closing of a registered offering in which the Company raised net proceeds of $3.6 million. This support from a new investor provides the company additional financial resources to execute on a funding strategy for the Phase 3 localized prostate cancer study. The company estimates that the cash and cash equivalents currently on hand will fund the Company through at least March 31, 2020.

- On October 21, 2019, the Company announced that following an End of Phase 2/ Pre-Phase 3 meeting with the United States Food and Drug Administration there is agreement regarding the design of a single Phase 3 clinical trial to evaluate the potential of topsalysin as a targeted focal therapy to treat patients with intermediate risk localized prostate cancer. The Phase 3 study design agreed upon with the FDA is consistent with the design previously agreed upon with the EMA. In addition, the FDA has indicated that in order to receive approval, we will need to evaluate all patients that progress to alternative treatments for an additional 12 months, for a total of 24 months of data, post the administration of the study drug. The Company believes that a single Phase 3 trial, if successful, will provide the clinical data necessary for approval in both the United States and Europe.

- From November 10-13, 2019, Sophiris CEO Randall E. Woods will attend the 25th Annual International Partnering Conference Bio-Europe 2019.

Financial Results:

At September 30, 2019, the Company had cash, cash equivalents and securities available-for-sale of $6.3 million and working capital of $3.1 million. The Company expects that its cash and cash equivalents and securities available-for-sale will be sufficient to fund its operations and debt service through March 2020, assuming no new clinical trials are initiated, and the Company continues operating as a going concern. The Company will require significant funding to advance topsalysin in clinical development and to continue its operations. As of September 30, 2019, the outstanding principal balance of the Company's term loan was $5.6 million. The Company began making principal payments on its term loan in April 2019.

For the three months ended September 30, 2019

The Company reported a net loss of $1.0 million or ($0.03) per share for the three months ended September 30, 2019, compared to net loss of $2.9 million or ($0.10) per share for the three months ended September 30, 2018.

Research and development expenses

Research and development expenses were $0.7 million for the three months ended September 30, 2019, compared to $1.8 million for the three months ended September 30, 2018. The decrease in research and development costs is primarily attributable to decreases in the costs associated with manufacturing activities for topsalysin and, to a lesser extent, a decrease in clinical costs associated with the Company's completed Phase 2b clinical trial of topsalysin for localized prostate cancer.

General and administrative expenses

General and administrative expenses were $1.4 million for the three months ended September 30, 2019, compared to $1.2 million for the three months ended September 30, 2018. Included as a component of general and administrative expense for the three months ended September 30, 2019 was $0.4 million of offering costs which were allocated to the common share purchase warrants issued in its August 2019 financing. These offering costs were allocated to general and administrative expense as the common share purchase warrants were classified as liabilities. General and administrative expenses included non-cash stock-based compensation expense of $0.1 million for the three months ended September 30, 2019 as compared to $0.2 million for the three months ended September 30, 2018.

Gain on revaluation of the warrant liability

Gain on revaluation of the warrant liability was $1.3 million for the three months ended September 30, 2019, compared to $0.2 million for the three months ended September 30, 2018. As the Company's warrants may require the Company to pay the warrant holders cash under certain provisions of the warrants, the Company accounts for the warrants as a liability, and the Company is required to calculate the fair value of these warrants each reporting date. 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 a material non-cash gain or loss being reported in the Company's consolidated statement of operations and comprehensive loss.

For the nine months ended September 30, 2019

The Company reported a net loss of $5.5 million or ($0.18) per share for the nine months ended September 30, 2019 compared to a net loss of $12.3 million or ($0.41) per share for the nine months ended September 30, 2018.

Research and development expenses

Research and development expenses were $3.4 million for the nine months ended September 30, 2019 compared to $8.7 million for the nine months ended September 30, 2018. The decrease in research and development costs was primarily attributable to decreases in the costs associated with manufacturing activities for topsalysin, and to a lesser extent, a decrease in clinical costs associated with the Company's completed Phase 2b clinical trial of topsalysin for localized prostate cancer.

General and administrative expenses

General and administrative expenses were $3.9 million for the nine months ended September 30, 2019 compared to $3.5 million for the nine months ended September 30, 2018. Included as a component of general and administrative expense for the nine months ended September 30, 2019 was $0.4 million of offering costs which were allocated to the common share purchase warrants issued in its August 2019 financing. These offering costs were allocated to general and administrative expense as the common share purchase warrants were classified as liabilities. General and administrative expenses included non-cash stock-based compensation expense of $0.4 million for the nine months ended September 30, 2019 as compared to $0.5 million for the nine months ended September 30, 2018.

Gain on revaluation of the warrant liability

Gain on revaluation of the warrant liability was $2.1 million for the nine months ended September 30, 2019 as compared to $0.1 million for the nine months ended September 30, 2018.

About Sophiris

Sophiris Bio Inc. is a late-stage clinical biopharmaceutical company developing topsalysin (PRX302) for the treatment of patients with urological diseases. Topsalysin has completed two Phase 2 clinical trials for the focal treatment of localized prostate cancer and has completed one Phase 3 study of topsalysin 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. For more information, please visit www.sophirisbio.com.

Certain statements included in this press release may be considered forward-looking, including the quotes of Sophiris' President and CEO and expectations about further development of topsalysin (PRX302), plans relating to execution of a Phase 3 clinical trial in localized prostate cancer, Sophiris' liquidity or capital requirements and the ability to obtain additional financing to fund a Phase 3 clinical trial and continue 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 clinical development, including the uncertainty of the design for any additional clinical trial of topsalysin in localized prostate cancer, risks that the Company will be able to fund future clinical trials or enter into a partnership or strategic transaction, risks about the Company's ability to continue as a going concern and other risks and uncertainties identified by Sophiris in its public securities filings with the Securities and Exchange Commission. 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)

	September 30, 2019	December 31, 2018
Assets:		
Current assets:		
Cash and cash equivalents	$ 4,251	$ 10,998
Securities available-for-sale	2,050	1,541
Prepaid expenses and other current assets	710	656
Total current assets	7,011	13,195
Property and equipment, net	3	4
Operating lease right-of-use	85	-
Total assets	$ 7,099	$ 13,199
Liabilities and shareholders' (deficit) equity:		
Current liabilities:		
Accounts payable	$ 431	$ 1,862
Accrued expenses	745	1,192
Current portion of promissory note	2,665	1,920
Operating lease liability	85	-
Total current liabilities	3,926	4,974
Long-term promissory note	3,086	5,091
Warrant liability	2,848	1,399
Total liabilities	9,860	11,464
Shareholders' (deficit) equity:		
Common shares, unlimited authorized shares, no par value; 33,572,140 and 30,205,915 shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively	131,489	131,247
Contributed surplus	27,459	26,714
Accumulated other comprehensive gain	100	100
Accumulated deficit	(161,809)	(156,326)
Total shareholders' (deficit) equity	(2,761)	1,735
Total liabilities and shareholders' (deficit) equity	$ 7,099	$ 13,199

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	**2018**	**2019**	**2018**

Operating expenses:				
Research and development	$ 738	$ 1,798	$ 3,382	$ 8,718
General and administrative	1,388	1,155	3,858	3,494
Total operating expenses	2,126	2,953	7,240	12,212
Other income (expense):				
Interest expense	(145)	(173)	(470)	(514)
Interest income	29	80	133	258
Gain on revaluation of warrant liability	1,281	153	2,105	143
Other income (expense), net	2	21	(11)	27
Total other income (expense)	1,167	81	1,757	(86)
Net loss	$ (959)	$ (2,872)	$ (5,483)	$ (12,298)
Basic and diluted loss per share	$ (0.03)	$ (0.10)	$ (0.18)	$ (0.41)
Weighted average number of outstanding shares – basic and diluted	32,072	30,111	30,841	30,111

Source: Sophiris Bio, Inc.