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

August 9, 2019

SAN DIEGO and VANCOUVER, British Columbia, Aug. 9, 2019 /PRNewswire/ -- Sophiris Bio Inc. (NASDAQ: SPHS) (the "Company" or "Sophiris"), 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 second quarter 2019 and recent corporate highlights.

"During the second quarter of 2019, we received positive feedback from the EMA regarding the design of our Phase 3 clinical trial for localized prostate cancer which was a significant step forward in our development of topsalysin," said Randall E. Woods, president and CEO of Sophiris. "We are now focused on our plan to fund this study and the Company going forward. We continue to believe that the ideal funding option will either be a potential development partnership or other strategic transaction and we are currently in discussions with multiple parties capable of funding the continued development of topsalysin."

Second Quarter Corporate Highlights:

- The Company received formal scientific advice from the European Medicines Agency (EMA) regarding a proposed design of a 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 by the EMA, will enroll patients with a confirmed diagnosis of intermediate risk disease. Approximately 700 men who meet the eligibility criteria will be equally randomized to receive a single administration of either topsalysin or placebo.
- The company is now actively engaged in discussions with the FDA on the design of the proposed Phase 3 clinical trial. The goal is to conduct a single Phase 3 trial, which if successful, will provide the clinical data for approval in both the US and Europe.
- The Company participated at both the H.C. Wainwright Global Life Sciences Conference and the 18th Annual Needham Healthcare Conference.

Financial Results:

At June 30, 2019, the Company had cash, cash equivalents and securities available-for-sale of $6.0 million and working capital of $1.8 million. The Company expects that its cash and cash equivalents and securities available-for-sale will be sufficient to fund its operations through November 2019, 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 June 30, 2019, the outstanding principal balance of the Company's term loan was $6.3 million. The Company began making principal payments on its term loan in April 2019.

For the three months ended June 30, 2019

The Company reported a net loss of $2.2 million or ($0.07) per share for the three months ended June 30, 2019, compared to net loss of $6.1 million or ($0.20) per share for the three months ended June 30, 2018.

Research and development expenses

Research and development expenses were $1.1 million for the three months ended June 30, 2019, compared to $3.6 million for the three months ended June 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 relatively consistent at $1.2 million for the three months ended June 30, 2019, compared to $1.1 million for the three months ended June 30, 2018.

Gain (loss) on revaluation of the warrant liability

Gain on revaluation of the warrant liability was $0.3 million for the three months ended June 30, 2019, compared to a loss of $1.4 million for the three months ended June 30, 2018. As the Company's warrants may require the Company to pay the warrant holder cash under certain provisions of the warrant, 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 six months ended June 30, 2019

The Company reported a net loss of $4.5 million or ($0.15) per share for the six months ended June 30, 2019 compared to a net loss of $9.4 million or ($0.31) per share for the six months ended June 30, 2018.

Research and development expenses

Research and development expenses were $2.6 million for the six months ended June 30, 2019 compared to $6.9 million for the six months ended June 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 relatively consistent at $2.5 million for the six months ended June 30, 2019 compared to $2.3 million for the six months ended June 30, 2018.

Gain (loss) on revaluation of the warrant liability

Gain on revaluation of the warrant liability was $0.8 million for the six months ended June 30, 2019 as compared to a loss of $10,000 for the six months ended June 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 the design and execution of a Phase 3 clinical trial in localized prostate cancer, Sophiris' liquidity or capital requirements and the ability to obtain additional financing or execute other strategic alternatives. 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 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.

Company Contact:	**Corporate Communications & Media Contact:**
Peter Slover	Jason Spark
Chief Financial Officer	Canale Communications
(858) 777-1760	619-849-6005
	jason@canalecomm.com

Sophiris Bio Inc.
Condensed Consolidated Balance Sheets

(In thousands, except share amounts)
(Unaudited)

	June 30, 2019	December 31, 2018
Assets:		
Current assets:		
Cash and cash equivalents	$ 4,972	$ 10,998
Securities available-for-sale	1,045	1,541
Prepaid expenses and other current assets	305	656
Total current assets	6,322	13,195
Property and equipment, net	3	4
Operating lease right-of-use	116	-
Total assets	$ 6,441	$ 13,199
Liabilities and shareholders' (deficit) equity:		
Current liabilities:		
Accounts payable	$ 566	$ 1,862
Accrued expenses	1,153	1,192
Current portion of promissory note	2,649	1,920
Operating lease liability	116	-
Total current liabilities	4,484	4,974
Long-term promissory note	3,758	5,091
Warrant liability	575	1,399
Total liabilities	8,817	11,464
Shareholders' (deficit) equity:		
Common shares, unlimited authorized shares, no par value; 30,217,140 and 30,205,915 shares issued and outstanding at June 30, 2019 and December 31, 2018, respectively	131,247	131,247
Contributed surplus	27,128	26,714
Accumulated other comprehensive gain	99	100
Accumulated deficit	(160,850)	(156,326)
Total shareholders' (deficit) equity	(2,376)	1,735
Total liabilities and shareholders' (deficit) equity	$ 6,441	$ 13,199

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Operating expenses:				
Research and development	$ 1,089	$ 3,591	$ 2,644	$ 6,920
General and administrative	1,218	1,096	2,470	2,340
Total operating expenses	2,307	4,687	5,114	9,260
Other income (expense):				
Interest expense	(159)	(172)	(325)	(341)
Interest income	43	91	104	178
Gain (loss) on revaluation of warrant liability	270	(1,365)	824	(10)
Other income (expense), net	(11)	36	(13)	7

Total other income (expense)	143	(1,410)	590	(166)
Net loss	$ (2,164)	$ (6,097)	$ (4,524)	$ (9,426)
Basic and diluted loss per share	$ (0.07)	$ (0.20)	$ (0.15)	$ (0.31)
Weighted average number of outstanding shares – basic and diluted	30,217	30,111	30,216	30,111

View original content to download multimedia:http://www.prnewswire.com/news-releases/sophiris-bio-reports-second-quarter-2019-financial-results-and-recent-corporate-highlights-300898918.html

SOURCE Sophiris Bio Inc.