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UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

FORM 8-K  
CURRENT REPORT

Pursuant to Section 13 or 15(d)  
of the Securities Exchange Act of 1934

August 9, 2019  
Date of Report (Date of earliest event reported)

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**Sophiris Bio Inc.**  
(Exact name of registrant as specified in its charter)

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**British Columbia**  
(State or other jurisdiction  
of incorporation)

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**001-36054**  
(Commission File Number)

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**98-1008712**  
(IRS Employer Identification No.)

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**1258 Prospect Street**  
**La Jolla, CA**  
(Address of principal executive offices)

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**92037**  
(Zip Code)

**Registrant's telephone number, including area code: (858) 777-1760**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligations of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 or Rule 12b-2 of the Securities Exchange Act of 1934.

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

**Securities registered pursuant to Section 12(b) of the Act:**

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Title of each class	Trading Symbol(s)	Name of each exchange on which registered
<b>Common Shares, no par value</b>	<b>SPHS</b>	<b>The Nasdaq Capital Market</b>

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**Item 2.02 Results of Operations and Financial Condition.**

On August 9, 2019, Sophiris Bio Inc. issued a press release announcing its financial results for the three and six months ended June 30, 2019. A copy of this press release is furnished herewith as Exhibit 99.1. Pursuant to the rule and regulations of the Securities and Exchange Commission, such exhibit and the information set forth therein and in this Item 2.02 have been furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to liability under that section nor shall they be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing regardless of any general incorporation language.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

99.1 [Press release dated August 9, 2019.](#)

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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

**Sophiris Bio Inc.**

Dated: August 9, 2019

By: /s/ Peter Slover \_\_\_\_\_  
Peter Slover  
Chief Financial Officer



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

**SAN DIEGO and VANCOUVER, British Columbia, August 9, 2019** – 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 18<sup>th</sup> 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](http://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:**

Peter Slover  
Chief Financial Officer  
(858) 777-1760

### **Corporate Communications & Media Contact:**

Jason Spark  
Canale Communications  
619-849-6005  
[jason@canalecomm.com](mailto:jason@canalecomm.com)



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

	<u>June 30, 2019</u>	<u>December 31, 2018</u>
<b>Assets:</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 4,972	\$ 10,998
Securities available-for-sale	1,045	1,541
Prepaid expenses and other current assets	305	656
<b>Total current assets</b>	<b>6,322</b>	<b>13,195</b>
Property and equipment, net	3	4
Operating lease right-of-use	116	-
<b>Total assets</b>	<b>\$ 6,441</b>	<b>\$ 13,199</b>
<b>Liabilities and shareholders' (deficit) equity:</b>		
<b>Current liabilities:</b>		
Accounts payable	\$ 566	\$ 1,862
Accrued expenses	1,153	1,192
Current portion of promissory note	2,649	1,920
Operating lease liability	116	-
<b>Total current liabilities</b>	<b>4,484</b>	<b>4,974</b>
Long-term promissory note	3,758	5,091
Warrant liability	575	1,399
<b>Total liabilities</b>	<b>8,817</b>	<b>11,464</b>
<b>Shareholders' (deficit) equity:</b>		
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)
<b>Total shareholders' (deficit) equity</b>	<b>(2,376)</b>	<b>1,735</b>
<b>Total liabilities and shareholders' (deficit) equity</b>	<b>\$ 6,441</b>	<b>\$ 13,199</b>



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

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2019</u>	<u>2018</u>	<u>2019</u>	<u>2018</u>
<b>Operating expenses:</b>				
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
<b>Other income (expense):</b>				
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)
<b>Net loss</b>	<u>\$ (2,164)</u>	<u>\$ (6,097)</u>	<u>\$ (4,524)</u>	<u>\$ (9,426)</u>
<b>Basic and diluted loss per share</b>	<u>\$ (0.07)</u>	<u>\$ (0.20)</u>	<u>\$ (0.15)</u>	<u>\$ (0.31)</u>
Weighted average number of outstanding shares – basic and diluted	<u>30,217</u>	<u>30,111</u>	<u>30,216</u>	<u>30,111</u>